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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 330, 340, and 372

[Docket No. APHIS-2018-0034]

RIN 0579-AE47

Movement of Certain Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations regarding the movement (importation, interstate movement, and environmental release) of certain genetically engineered organisms in response to advances in genetic engineering and our understanding of the plant pest risk posed by genetically engineered organisms, thereby reducing regulatory burden for developers of organisms that are unlikely to pose plant pest risks. This final rule, which marks the first comprehensive revision of the regulations since they were established in 1987, provides a clear, predictable, and efficient regulatory pathway for innovators, facilitating the development of new and novel genetically engineered organisms that are unlikely to pose plant pest risks.

DATES: Effective [Insert date 60 days after date of publication in the Federal Register, except for § 340.4 and § 340.5, which are effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Dr. Alan Pearson, Assistant Deputy Administrator, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 98, Riverdale, MD 20737-1238; (301) 851-3944.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) administers the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests" (referred to below as the regulations).

These regulations govern the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered (GE) organisms.

Along with the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA), APHIS is responsible for the oversight and review of GE organisms. In 1986, the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework)[1] was published by the Office of Science and Technology Policy. It describes the comprehensive Federal regulatory policy for ensuring the safety of biotechnology research and products and explains how Federal agencies use existing Federal statutes to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework explains the regulatory roles and authorities for APHIS, EPA, and the FDA.

APHIS first issued these regulations in 1987 under the authority of the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912, two acts that were subsumed into the Plant

[1]To view the framework, go to https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.

Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) in 2000, along with other provisions. Since 1987, APHIS has amended the regulations six times, in 1988, 1990, 1993, 1994, 1997, and 2005, to institute exemptions from the requirement for permits to conduct activities for certain microorganisms and *Arabidopsis*, to institute the current notification process and petition procedure, and to exclude plants engineered to produce industrial compounds from the notification process.

While the regulations have been effective in ensuring the safe introduction of GE organisms during the past 30 years, advances in genetic engineering have occurred since they were promulgated. APHIS has now accumulated three decades of experience in evaluating GE organisms for plant pest risk. The Agency's evaluations to date have provided evidence that genetically engineering a plant with a plant pest as a vector, vector agent, or donor does not in and of itself result in a GE plant that presents a plant pest risk. Additionally, genetic engineering techniques have been developed that do not employ plant pests as donor organisms, recipient organisms, vectors, or vector agents yet may result in GE organisms that pose a plant pest risk. Given these developments, as well as legal and policy issues discussed below, it has become necessary, in our view, to update our regulations accordingly.

On January 19, 2017, we published in the *Federal Register* (82 FR 7008-7039, Docket No. APHIS-2015-0057) a proposed rule[2] intended to revise our regulatory approach from "regulate first before analyzing risks" to "analyze plant pest and noxious weed risks of GE organisms prior to imposing regulatory restrictions."

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[2] To view the 2017 proposed rule, the subsequent withdrawal, all supporting documents, and comments APHIS received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0057.

Under the January 2017 proposed rule, a stakeholder could request that we conduct a risk assessment to determine whether a GE organism would pose plant pest or noxious weed risks and thus need to be regulated. Regulated GE organisms could be imported, moved interstate, or released into the environment under a flexible, risk-based permitting procedure.

APHIS received 203 comments on the proposal during the comment period. Commenters expressed concerns about many provisions of the proposed rule. Many thought that the proposed requirements would be too burdensome and had the potential to stifle innovation.

After reviewing the comments, APHIS subsequently withdrew the proposed rule. Following the withdrawal, APHIS conducted extensive outreach to Land Grant and public university researchers, as well as small-scale biotechnology developers, agriculture innovators, and other interested stakeholders. In total, APHIS met with more than 80 organizations, including 17 universities, State departments of agriculture, and farmer organizations. Much of the feedback received during this process centered on the need to focus regulatory efforts and oversight upon risk, rather than the method used to develop GE organisms. Stakeholders also expressed a desire for flexible and adaptable regulations so that future innovations do not invalidate the regulations. We also received feedback urging us to keep international trade objectives in mind when proposing new regulations and ensuring that new regulatory requirements are transparent and clearly articulated.

The feedback we received led us to develop a new regulatory framework, one that entailed focusing our regulatory efforts on the properties of the GE organism itself rather than on the method used to produce it. We believed that this new regulatory approach would better reflect our current knowledge of the field of biotechnology and would therefore enable us to evaluate GE organisms for plant pest risk with greater precision than the existing framework

allowed. The new regulatory framework was also intended to enable APHIS to avoid conducting repetitive analyses, to utilize its staff time more efficiently than before, and to provide better stewardship of taxpayer dollars.

On June 6, 2019, we published in the *Federal Register* (84 FR 26514-26541, Docket No. APHIS-2018-0034) a proposal[3] to amend the regulations in accordance with the Secretary of Agriculture's March 28, 2018, statement that provided clarification on the USDA's oversight of plants produced through plant breeding innovations. (The statement and further details are available at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/2018_brs_news/plant_breeding.)

We solicited comments on our proposed rule and its supporting analyses until August 6, 2019. We received 6,150 comments by that date. They were from developers of GE organisms; growers of GE plants for food crops and other uses; trade associations representing both of those groups and sellers of such commodities as corn, soybeans, and grain; scientists representing academic institutions; organic farmers and trade associations representing their interests; consumer and public interest groups; and individuals. The comments are discussed below by topic.

Applicability of the Regulations

Exemptions.

The June 2019 proposed rule exempted from the regulations certain categories of modified GE plants. Specifically, § 340.1(b)(1) through (b)(4) exempted such plants if:

- The genetic modification is solely a deletion of any size; or

[3] To view the proposed rule and the comments we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0034.

- The genetic modification is a single base pair substitution; or
- The genetic modification is solely introducing nucleic acid sequences from within the plant's natural gene pool or from editing nucleic acid sequences in a plant to correspond to a sequence known to occur in that plant's natural gene pool; or
- The plant is an offspring of a GE plant and does not retain the genetic modification in the GE plant parent.

In addition to above-listed categories, under proposed § 340.1(c), we stated that GE plants would not be subject to the regulations if they have plant-trait-mechanism of action (MOA) combinations that are the same as those of GE plants that APHIS has found, after conducting a regulatory status review (RSR), as described later in this document, not to be subject to the regulations under part 340.

Several commenters stated that APHIS did not provide the "necessary scientific justifications" for the exemptions from regulation listed in proposed § 340.1(b)(1) through (b)(3). One commenter stated that the proposed exemptions do not consider potential pest risks or human, environmental, or agricultural impacts on nontarget organisms. Another commenter claimed that APHIS regulates risks other than plant pest risks, such as inadvertent introduction to the food supply and economic impacts from gene flow, so there should be scientific evidence that plants exempted from regulations do not pose any of the full range of risks.

For the reasons discussed below, APHIS will not be making any changes to the final rule in response to these comments.

The exemptions in paragraphs (b)(1) through (b)(3) are based on the principles listed below. (For reasons discussed later in this document, we are removing from this final rule the exemption contained in paragraph (b)(4) of the proposed rule; while there is still a paragraph (b)(4) in this final rule, it serves a different purpose.)

- Plants created through traditional breeding have a history of safe use;
- The types of plants that qualify for these exemptions can also be created through traditional breeding; and
- There is no evidence for unique hazards inherent in the use of recombinant deoxyribonucleic acid (DNA) or genome editing techniques.

When a modified plant meets one of the above-listed exemptions, therefore, it should not pose plant pest risks greater than the plant pest risks posed by plants modified by traditional breeding methods and thus should rightly not be subjected to regulation under this part.

We noted in the preamble to the June 2019 proposed rule that traditionally bred crops have a long history of safe use and that the long history of traditional plant breeding gives us extensive experience in safely managing any associated plant pest risks. Thus, U.S. regulatory agencies do not evaluate traditionally bred new crop varieties for health and environmental safety prior to commercial release. Although traditional breeding is not risk free, the risks associated with it are, according to a 1989 National Research Council (NRC) report[4], "manageable by accepted standards." Where safety risks have been found to occur, all of the cases noted were increased levels of endogenous plant compounds that resulted from attempts to

[4] NRC 1989. Field Testing Genetically Modified Organisms: Framework for Decisions NAP http://www.nap.edu/catalog/1431.html

increase crop resistance to pests that also resulted in toxicity to mammals[5]. Familiarity with endogenous toxins and allergens and improved analytical methods are now routinely used to verify that such compounds are not elevated during the breeding process. In other words, the types of traits that can be introduced through traditional breeding have not generally led to plant pest risk concerns.

The types of DNA modifications that occur through traditional breeding are well characterized (Oladosu *et al.* 2016; Kharkwal *et al.* 2012). Among the common mutations used in traditional breeding are double strand breaks that result in deletions, insertions, inversions, or translocations of DNA and base pair substitutions (Oladosu *et al.* 2016). These types of modifications occur at a low rate from naturally occurring environmental exposure to ionizing radiation, radical oxygen, chemical compounds, or biological agents such as viruses or at an elevated rate in response to radiation and chemical mutagenesis. In traditional breeding, these types of DNA modifications occur somewhat randomly and individual plants possessing a mutation conferring a useful phenotype are isolated by screening. Innovative technology can be used to create targeted double strand breaks in specific parts of the genome that when repaired result in deletions and small insertions just like from natural environmental exposure or radiation mutagenesis (Chen *et al.* (2019). Likewise, innovative technology can also be used to create base pair substitutions similar to the modifications that can be created by random chemical mutagenesis, but in a specific, targeted manner. In other words, precisely the same types of DNA modifications that occur in traditional breeding can also be constructed using innovative technology (Custers *et al.* 2019). We are exempting plants generated using plant breeding innovations that have these two types of modifications, deletion and base pair substitution,

[5] NRC 2004. Safety of Genetically Engineered Foods http://www.nap.edu/catalog/10977.html

because they could otherwise be created by traditional breeding and pose no increased plant pest risk relative to their traditionally bred counterparts.

The exemption in proposed paragraph (b)(3) applies to the use of innovative technology to recreate the introduction of an allele or an edit that could otherwise be introduced by crosses. Crossing has been used to introduce alleles into breeding populations since the early 18th century (Goulet *et al.* 2017). More recently, technology has expanded how genetic material can be introduced into breeding populations through wide crosses, embryo rescue, and protoplast fusion (Bravo *et al.* 2011; De Filippis, 2014; Singh, 1990). Innovative technology can be used to introduce a genetic sequence from any donor source into plants. To limit the exemption to what is possible in traditional breeding, the third exemption only applies to the introduction of an allele known to occur from a donor source into the same species as the donor source or into a species compatible to wide crosses, embryo rescue, or protoplast fusion with the donor species.

The NRC has concluded in multiple studies[6] that there was no evidence of unique hazards inherent in the use of recombinant DNA techniques and with respect to plants, and that crops modified by molecular and cellular methods should pose risks no different from those modified by classical genetic methods for similar traits. New molecular genome editing techniques are more specific than recombinant DNA techniques and plants modified by these techniques similarly should pose risks no different from those modified by classical genetic methods for similar traits.

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[6] National Academies of Sciences, Engineering, and Medicine (NAS) 1987. Introduction of Recombinant DNA-engineered Organisms into the Environment: Key Issues. Washington, D.C.: National Academy Press.24 pp.; NRC 1989. Field Testing Genetically Modified Organisms: Framework for Decisions NAP [HYPERLINK "http://www.nap.edu/catalog/1431.html"]; NAP 2016 Genetically Engineered Crops: Experiences and Prospects. 420 pp http://www.nap.edu/23395.

APHIS considers impacts on nontarget organisms that are beneficial to plants to be indirect plant pest impacts. It is not accurate to say that APHIS has previously regulated risks other than plant pest risks. Under the current regulations, APHIS has imposed measures to limit gene flow from GE plants that meet the definition of a regulated article during confined field trials. In these cases, the Agency considered the GE plants to be regulated articles that could therefore pose a plant pest risk. In cases where GE crops were not subject to regulation, no "other risks" such as inadvertent introduction to the food supply or economic impacts from gene flow have been regulated by the Agency.

A commenter opposed the exemptions listed in proposed § 340.1(b)(1) through (b)(3) on the basis that plants produced through most methods that would be used for genome editing are regenerated from single cells in tissue culture, resulting in somaclonal variation with unpredictable consequences, and that off-target mutations caused by genome editing are more likely than chemical and radiation mutagenesis to be non-random. A second commenter asked that the exemptions be limited so that they apply only to plants produced using techniques that minimize off-target mutations. A third commenter asked whether off-target mutations are considered when determining eligibility for an exemption.

Somaclonal variation has been utilized extensively for breeding purposes and the resultant new plant variety is currently not subjected to these regulations (Krishna *et al.* (2016); Neelakandan, and Wang (2012). APHIS is not aware of a reason to mandate government oversight of new plant varieties resulting from somaclonal variation.

Background mutation occurs naturally in plants and does not raise plant pest risk concerns in traditional breeding programs. APHIS does not believe it is necessary to regulate off-target effects of genome editing in plants because the off-target mutation rate from genome

editing is low relative to the background mutation rate and whatever changes do occur are likely to be segregated away from the target mutation during the breeding process. Comprehensive CRISPR/Cas off target analysis on a genome-wide scale has been performed in rice, maize, tomato, and Arabidopsis (Feng *et al.* (2014); Feng *et al.* (2018); Peterson *et al.* (2016); Nekrasov *et al.* (2017) Lee et al (2018); Tang et al (2018)). In these cases where the frequency of off-target mutation was measured in CRISPR/Cas expressing lines and their progeny, the authors concluded that the rate of off-target mutation was below the level of background mutation induced during seed amplification or tissue culture (Hahn and Nekrasov, 2019). Due to the nature of plant breeding where populations are created, evaluated and individuals advanced for further breeding, off-target changes are likely to be lost unless they are genetically linked to the targeted modification. APHIS wishes to clarify that, for these reasons, off-target mutations are not considered when determining eligibility for an exemption, and has modified the regulatory text on exemptions to indicate that we are only considering targeted modifications when determining eligibility for an exemption.

Some commenters stated that the scope of the exemptions listed in proposed § 340.1(b)(1) through (b)(3) should be broadened to encompass the range of genetic modifications that are accessible to plant breeders through traditional breeding techniques, proposing alternative language that would allow an unlimited number of genetic modifications to be made and exempt from the regulations.

The commenters appear to have interpreted "could otherwise have been developed through traditional breeding techniques" to mean any type and extent of genetic change that is theoretically possible through traditional breeding techniques. There are many biological and practical factors that affect a plant breeder's ability to develop a new crop variety by introducing

genetic variation and intentionally selecting for desired traits. These factors, and thus the extent of intentionally selected genetic variation that can be introduced, vary widely between plant species. Therefore, for the purposes of part 340, APHIS is clarifying that the exemptions listed in § 340.1(b)(1) through (b)(3) are based on measures that are easily recognizable and on genetic changes that could be achieved by traditional breeding methods in any plant species in an agriculturally relevant timeframe (Custers *et al.* 2019).

With that said, new plant breeding innovations have the capability of enormously accelerating the breeding process, making possible scales of genomic change which could not be achieved through traditional breeding methods (Wolter *et al.* (2019); Najera *et al* (2019)). Developing a universal regulatory standard, at this time, that covers any plant modification that has been or might in the future be produced using techniques based on what could be achieved with traditional breeding methods is not a practical expectation. As such, we are revising § 340.1(b) to establish a process for listing additional modifications plants can contain and still be exempted from the regulations. This process is specified in paragraph (b)(4) of § 340.1 in this final rule.

Some commenters have inquired how the exemptions in proposed § 340.1(b)(1) through (b)(3) pertain to combinations of genetic modifications or to sequential edits. For example, would a deletion and a single base substitution made at the same time in a plant qualify for exemption? If a single change is made to a plant, when could another change be made that qualified for an exemption? Some commenters argued that there is no valid scientific reason that the exemptions should not allow multiple simultaneous genomic changes to be made. Other commenters asked us to reaffirm that the exemptions are limited to only a single genome editing change, and that a plant containing multiple changes made at the same or different times would

not be exempt, or that we delete the exemptions altogether, since genome edits could be made sequentially such that each intermediate organisms would be exempt, cumulatively resulting in a final organism with many targeted changes that would also be exempt. Several commenters requested that APHIS include a process for adding new categories of exemptions and revising exemptions in order to ensure that the regulatory system stays up to date and keeps pace with advances in scientific knowledge, evidence, and experience.

APHIS seeks to clarify that exemptions listed in § 340.1(b)(1) through (3) apply to plants containing single targeted modifications. The exemptions were formulated to conservatively apply to what could otherwise be achieved through traditional plant breeding techniques in any species because APHIS will not be reviewing plants that qualify for the exemptions. APHIS realizes that in some species, a single targeted modification is often less than what could otherwise be developed through traditional breeding. However, as noted above, the extent of intentionally selected variation that could otherwise be introduced through traditional breeding varies depending on the plant species. To establish clear and unambiguous exemptions that could apply to any plant species while enabling for variation in what can be achieved through traditional breeding, APHIS has revised the regulatory text in § 340.1(b).

Initially, the exemptions will apply only to plants containing a single modification in one of the categories listed. APHIS anticipates scientific information and/or experience may, over time, allow APHIS to list additional modifications plants can contain and still be exempted from the regulations so that the regulatory system stays up to date and keeps pace with advances in scientific knowledge, evidence, and experience. If the Administrator determines that it is appropriate to list additional modifications, APHIS will notify the public through a notice published in the notice section of the *Federal Register* and take public comment. After

reviewing the comments, APHIS will issue a subsequent notice announcing its determination, as provided in new paragraph (b)(4).

One commenter requested that APHIS document examples where deletions of any size could be made by traditional breeding.

The first exemption allows any size deletion because radiation can create any size deletion. As mutations are typically detrimental to the organism, what is achievable in practice is limited by the viability and fertility of the organism. Large mutations can be maintained in a heterozygous state but do not tend to undergo homozygous inheritance (Naito 2005). For example, in Arabidopsis, which has a genome size of 135 Mb (Arabidopsis Genome Initiative 2000), a radiation-induced deletion of 3.1 Mb was obtained that disrupted 852 genes and was maintainable only as a heterozygote presumably because genes essential for survival are present in the deleted region (Kazama *et al.* 2017). Polyploid plants and those with large genomes are better able to accommodate even larger deletions (Men *et al.* 2002). For example, in hexaploid wheat, X-ray mutagenesis was used to create a mutant, Ph1-, widely used in breeding programs, that has a 70 Mb deletion (Sears 1977). To put the size of this deletion in perspective, it is larger than half of the entire genome of Arabidopsis.

Some commenters recommended that the exemption in paragraph (b)(1) be broadened to allow for insertions that occur during the natural DNA repair mechanism after double-strand break of the DNA. In the proposed rule, the exemption in (b)(1) only mentions deletions.

APHIS agrees with the comment. Deletions, small insertions, and combinations of deletions and insertions are all possible outcomes resulting from the cellular mechanisms used to repair DNA breaks that occur naturally or that are induced during traditional plant breeding, and all have been used in traditional plant breeding (Manova and Gruszka. 2015; Wang et al., 2016).

The exemption in paragraph (b)(1) has been revised to reflect all of the possible outcomes of natural DNA repair mechanisms that occur in the absence of a deliberately provided repair template.

A commenter asked that APHIS eliminate the exemptions for deletions and single base pair substitutions, arguing that any type of change in a gene sequence can potentially cause phenotypic changes that have significant consequences.

APHIS disagrees that the exemptions should be eliminated on the basis that any type of sequence change can potentially cause phenotypic changes that have significant consequences. Naturally occurring single base pair substitutions and deletions are commonly induced and widely used to generate new crop varieties in traditional mutation breeding (Oladosu *et al.* 2016; Kharkwal. 2012; Ahloowalia and Maluszynski 2001). The targeted single base pair substitutions or deletions covered by these exemptions are the same in kind as, and do not pose any increased plant pest risks than, the substitutions or deletions introduced through traditional breeding. Thus, they should not be subject to regulations.

Many commenters argued that limiting the exemption in proposed § 340.1(b)(1) to a single deletion and the exemption in (b)(2) to a single base pair substitution does not take into account that multiple base pair substitutions and/or deletions are routinely and safely introduced into plants using traditional breeding methods, including mutagenesis.

The argument that multiple substitutions or deletions can occur through traditional breeding methods, including mutagenesis, seems to be conflating the specific targeted changes that can be made via genome editing techniques with the multiple random changes that occur during traditional breeding, only one or several of which might contribute to the desired phenotype. APHIS recognizes that in many plant species it is possible to introduce more than one

specific deletion or base pair substitution through traditional breeding techniques when the modifications are not closely linked genetically. However, the exemptions listed in § 340.1(b) are based on measures that are easily defined and include genetic changes that could practically be achieved by traditional breeding methods in any plant species in an agriculturally relevant timeframe. It is not possible to define a number of changes greater than one which would apply to all species. The number of changes that can be achieved through traditional breeding techniques can vary widely from one species to another depending on the biological and practical factors discussed earlier. For this reason, APHIS is retaining the limitation of a single modification as this approach ensures that we can identify those plants that pose a plant pest risk. We anticipate that most plants that are not eligible for the exemption and do not pose a plant pest risk will pass through the RSR process quickly.

In addition, as noted above, we are revising § 340.1(b) by adding a new paragraph (b)(4) that establishes a process for listing additional modifications plants can contain and be exempted from the regulations based on what could be achieved through traditional plant breeding. Thus, while the exemptions will initially apply only to plants containing a single modification in one of the categories listed, APHIS anticipates scientific information and/or experience may, over time, allow multiple and sequential changes after public notice and comment.

Some commenters suggested a change to the exemption in proposed § 340.1(b)(2) so that it would allow a limitless number of synonymous base pair changes. Synonymous base pair changes, it was stated, do not alter the amino acid composition of the encoded protein. One commenter suggested changing the exemption to allow however many specific and known base pair changes are needed to achieve the intended MOA.

APHIS rejects the first suggestion because synonymous changes can lead, and indeed would have been made, to generate significant phenotypic changes, e.g., by altering mRNA splice sites, promoters, and regulatory RNAs. APHIS acknowledges that these types of phenotypic changes could, in principle, also occur through a single deletion or base pair change in traditional breeding. However, these types of phenotypic changes are unlikely to be possible in all or perhaps even most genes through deletion or single base pair changes. As explained above, multiple targeted changes are not likely in traditional breeding, so the exemption will not be broadened to include multiple synonymous base pair changes. However, as discussed below, we have revised the exemption in paragraph (b)(3) to clarify that if multiple sequence changes are needed to generate an allele that will result in the intended phenotype and those changes are known to occur in the plant's gene pool, the modified plant would qualify for the exemption.

One commenter stated that APHIS should eliminate the exemption in (b)(3) regarding introducing variation known to occur in the gene pool because sequences found naturally in closely related, sexually compatible organisms do not necessarily have acceptable risks when introduced into other species. The commenter offered an example, stating that "the introduced nucleic acids can direct the synthesis of toxins, change metabolism in harmful ways, turn on or off genes and metabolic pathways in the genetically engineered host, and make the genetically engineered organism more susceptible to pests and pathogens, or more fit in the wild and more weedy."

APHIS disagrees with the comment. The commenter is pointing out harms that potentially could occur in traditional breeding programs. However, such harms have not materialized in traditional breeding programs because they rarely occur and would be eliminated during the evaluation and selection process.

One commenter wished to know whether the exemption in proposed § 340.1(b)(3) supersedes the exemption in § 340.1(b)(1) and (b)(2). Another commenter felt that the exemptions in (b)(1) and (b)(2) were too narrow because polymorphisms, insertions, inversions, and multiple megabase deletions and translocations are abundant in nature and frequently induced in breeding programs through mutagenesis.

APHIS seeks to clarify that § 340.1(b)(3) does supersede paragraphs (b)(1) and (b)(2) in the number of changes that can be made under the exemption. APHIS also seeks to clarify that paragraphs (b)(1) and (b)(2) pertain to products of mutagenesis which are not known to occur in the genepool, whereas (b)(3) only applies to variation previously known to occur. Therefore, the exemption in (b)(3) allows the introduction of an allele (a variant form of a gene or, for the purposes of this regulation, a genetic sequence) containing multiple sequence changes as long as the allele is known to occur in the gene pool of the plant. With regard to the comment that the exemptions in paragraphs (b)(1) and (b)(2) are unnecessarily restrictive because there are changes abundant in nature not covered by these exemptions, APHIS wishes to clarify that the duplications, inversions, translocations, and transpositions already known to occur in the gene pool would qualify under the exemption in (b)(3).

Some commenters suggested deleting "natural" from paragraph (b)(3) because the gene pool of a plant may include variation that has been previously induced through chemical or radiation mutagenesis or that could be introduced via human-assisted wide crosses. Further comments on the exemption in (b)(3) recommended substituting the phrase "known to occur" with some variation of "otherwise accessible through traditional plant breeding methods."

APHIS agrees with the first comment and disagrees with the second. APHIS considers the known and accessible gene pool of a plant to include not only genetic sequences that can be introduced to a plant via crosses that can take place without human assistance, but also human-assisted wide crosses between distantly related species. In systems for which breeding techniques such as bridging and embryo rescue have been developed to enable wide crosses, distantly related plants are also considered part of the known gene pool. However, these categories may not be considered "natural," so APHIS is in favor of deleting this term. APHIS is retaining the phrase "known to occur," however. As discussed above, the statement "could otherwise have been developed through traditional breeding techniques" does not refer to any genetic changes that are theoretically possible. Almost any genetic change is theoretically possible, given enough time. APHIS' intention is to exempt from regulation a product that could be practically expected to be pursued and achieved in a traditional breeding program. To qualify for an exemption based on occurrence in the gene pool, the genetic change and its phenotypic consequence must be known to occur. We do not intend the exemption to apply to limitless possibilities that are theoretically possible but not currently known to occur in the gene pool. Consequently, the exemption in (b)(3) has been slightly modified for accuracy and clarity.

Some commenters asked that the exemption in paragraph (b)(3) be expanded to include plants in which an allele has been modified to align with a similar known allele found in a close relative, or in a more distant relative beyond the family level of taxonomy, or that we exempt plants containing any sequence from a plant that is known not to be a plant pest and is routinely used for food.

APHIS considers the known and accessible gene pool of a plant to include not only genetic sequences that can be introduced to a plant via crosses that can take place without human

assistance, but also human-assisted wide crosses between more distantly related species. In systems for which breeding techniques such as bridging and embryo rescue have been developed to enable wide crosses, more distantly related plants are also considered part of the known gene pool. APHIS agrees in principle that exchange of genetic information between unrelated species is likely to be safe in most cases. However, APHIS does not have the experience to definitively state that exempting all exchange of DNA between plants will not lead to increased plant pest risk. In cases where genetic material from a more distantly related plant species is introduced into the modified plant, developers can request a regulatory status review.

A commenter stated that their understanding is that the exemption in (b)(3) would include any insertion or other sequence modification of less than 20 base pairs. APHIS disagrees and seeks to clarify that any insertion or sequence modification of 20 base pairs would not qualify for exemption (b)(3). The exemption does not apply to what is theoretically possible. The genetic variation must be known to occur in the plant's gene pool in order to qualify for the exemption.

A commenter stated that the regulation could clarify that exemption (b)(3) covers the introduction of natural or chemically synthesized copies of nucleic acid sequences from one plant species into the same or a crossable plant species, including a) the targeted insertion or replacement of sequences exceeding 20 base pairs in length (e.g., the insertion or replacement or a promoter, terminator, exon, intron, or small open reading frame, excluding complete genes), b) the targeted replacement of a cisgenic allele (i.e. perfect allelic replacement), c) the targeted insertion of a cisgenic sequence at the same or a different location in the genome of the recipient species, and d) the targeted insertion of a cisgene with a new combination of genetic elements, as plants containing such changes could have occurred naturally or could result from traditional breeding since they fall under exemption (b)(3). A second commenter stated that some genetic

engineering experiments will replace promoters, altering gene expression patterns in ways not attainable by today's breeders.

APHIS does not intend to modify the regulation text per the commenter's suggestion. The exemptions are based on genetic changes that could practically be achieved by traditional breeding methods in any plant species in an agriculturally relevant timeframe. Thus, many but not all of the examples provided by the first commenter are not eligible for exemption (b)(3). If a developer has a question about whether their plant is exempt from the regulation, they can contact APHIS for a consultation.

Some commenters asked how the deletion exemption in paragraph (b)(1) pertains to diploid and polyploid plants. For example, if a deletion is made to both alleles of a diploid or all four or six alleles in tetraploid and hexaploid plants, respectively, would those plants qualify for the exemption?

APHIS seeks to clarify that exemptions in paragraphs (b)(1) through (b)(3) apply to modifications made to one pair of homologous chromosomes. It is very straightforward in classical breeding to identify a single allele in a diploid line and then convert the heterozygote to a homozygote in the next generation. However it is very difficult through traditional breeding to create the same allele in all homeologous genomes in polyploid plants. Therefore, for polyploid plants, the exemption would only apply to modifications made to one pair of homologous chromosomes.

Some commenters noted that the exemption in proposed § 340.1(b)(4), i.e., the exemption of null segregants derived from GE plants, is superfluous because the definition of *genetic engineering* only applies to organisms whose DNA sequence has been modified.

APHIS agrees with these commenters. According to our definition of *genetic engineering,* the genome of null segregants has not been created or modified. Therefore null segregants do not need an exemption from regulation, and APHIS is removing this exemption from the final rule.

Some commenters stated that the exemption in proposed § 340.1(c) for a GE plant with a plant-trait-MOA combination that has previously undergone an analysis in accordance with § 340.4 and has been found by the Administrator to be unlikely to pose a plant pest risk should be eliminated. One commenter stated that the impact of releasing new GE plants into the environment cannot be accurately predicted or assessed without case-by-case analysis and controlled field experiments. Another commenter stated that every transformation event is unique, and thus potentially has a novel phenotype that must be assessed to determine appropriate regulation. The commenter further stated that the National Academy of Sciences (NAS) has also advocated the use of genetic engineering [i.e., transformation] as "both a useful and scientifically justifiable regulatory trigger" because "there is no scientific basis" on which to exclude GE organisms from regulatory review prior to evaluation of data on the interactions between "trait, organism and environment."

APHIS disagrees with the assertion that every transformation event has a novel phenotype that must be assessed to determine appropriate regulation and that controlled field experiments are always necessary for assessment. Based on the risk assessments we have performed in accordance with the petition process over 30 years, we have determined that, in many cases, we would have been able to evaluate the plant pest risks associated with a GE organism without field-test data. Rather, the Agency has discovered that the introduced trait of the GE organism provides the most reliable indicator of the organism's potential for deleterious

effects on plants and plant products. These observations are expected and are consistent with the findings of reports of NAS (NRC 1989; NAS 2016). APHIS will seek additional information, potentially including data from controlled field experiments, in cases where APHIS identifies a plausible pathway to increased plant pest risk.

The same NAS study (NRC, 2002) cited by the commenter stated the following: "Transgenic organisms have potential environmental risks, but the committee expects that most of them will not produce significant actual environmental risks. Consequently, the committee also suggests that for environmental risk regulatory oversight should be designed to winnow the potentially riskier transgenic crops from the less risky ones before a substantial regulatory burden is imposed on the less risky ones." APHIS has designed a system where organisms that pose a plausible plant pest risk are rapidly distinguished from those that do not, based on the RSR process described below, focusing regulation on the former. The exemption in § 340.1(c) will only apply to those GE plants that have undergone a risk assessment in the RSR process. The revised regulations are proportionate to risk and are therefore consistent with the recommendation of NAS's study.

Several comments were received on the definition and application of the term MOA as it relates to the exemption in § 340.1(c). Two commenters stated that the categories of trait (defined in the June 2019 proposed rule as an observable (able to be seen or otherwise identified) characteristic of an organism) and MOA (defined as the biochemical process(es) through which genetic material determines a trait) could be interpreted so broadly that new GE plants that have a similar plant-trait-MOA combination to a nonregulated plant yet contain unique features with unknown impacts on non-target organisms and the surrounding ecosystem would not require review by APHIS. They stated that, for example, the "Cry protein MOA" could include dozens

of possibilities with unknown effects and that it could even be the case that APHIS review would not be required when any gene encoding a Cry protein that targets broad orders of insect pests is inserted into a plant that had previously been engineered with any other trait and found by APHIS not to pose a plant pest risk. Another commenter stated that reasonably broad MOA categories should be established that would cover broad protein functional classes, account for all normal polymorphisms found in nature at the DNA and protein levels at the genus level, and account for the normal wide variation in expression seen among transgenic events and backgrounds. A third commenter requested that the final rule clarify which products would qualify for the exemption in § 340.1(c), noting that APHIS alternately used the terms "same" and "similar" to describe products that could qualify based on their use of a crop-trait-MOA that has already been assessed by the Agency and determined unlikely to pose a plant pest risk than the appropriate comparator(s). A fourth commenter recommended that the definition of MOA refer to the biochemical process(es) through which the gene, rather than the genetic material, determines a trait, stating that it is a gene product and not the genetic material that determines the resulting biochemical process.

APHIS disagrees that the proposed definition of MOA is too broad. The concerns of the commenters are based on misreading the definitions and the preamble of the June 2019 proposed rule. The preamble was clear that the MOA refers to the specific manner by which the genetic modification confers the intended trait on the plant, pointing out that the same trait can be obtained by different MOAs that would thus be subject to distinct RSRs. In the example cited, the preamble was clear that non-target impacts related to Cry proteins depend on whether the nontarget insect has the correct receptor in its gut to bind the Cry protein; thus, for each new Cry protein it will be important to evaluate the potential for non-target impacts. Similarly, the

preamble provided an example of ribonucleic acid interference-based resistance, where it would be important to consider the specific target RNA and its corresponding protein in order to determine whether there could be non-target effects. Moreover, the regulatory text and preamble were clear that it is the specific plant-trait-MOA that is the subject of the RSR and decision. Developers could not insert any cry gene that encodes a protein targeting a broad order or orders of insects into a plant that has already been engineered with any other trait-MOA combination previously reviewed by APHIS and claim that the plant is exempt from regulation under 340.1(c). APHIS agrees that in most cases the MOA could cover all normal polymorphisms of a gene found in nature, even at levels broader than the genus. For example, the outcome of an RSR would apply to genetic material encoding an enzyme that catalyzes a specific biochemical reaction regardless of whether the genetic material is sourced from a plant or a microbe, as long as the enzyme catalyzes the same biochemical reaction regardless of the organism from which the genetic material encoding the enzyme is obtained, and does not catalyze any additional biochemical reactions that differ among the source organism. APHIS does not agree that the MOA would be so broad as to cover broad functional classes, since broad functional classes could encompass many different proteins that have multiple differences in the biochemical processes in which they participate. Regarding variation in expression, in most cases APHIS anticipates that variation in expression should not affect the outcome of an RSR. However, as we noted in the preamble to the June 2019 proposed rule, there may be cases where it is important to consider where, when, or at what level the genetic material is expressed in the plant. In those cases, APHIS will specify whether and in what way variation in expression limits the outcome of the review. For this reason, APHIS will not revise the definition of MOA, since some MOAs may not involve changes in gene products but rather changes in genetic material

that affect the expression of gene products. As this discussion makes clear, a plant-trait-MOA combination must be the same as a previously reviewed plant-trait-MOA combination that has been found to be unlikely to pose a plant pest risk in order to qualify for the exemption.

One commenter urged that in addition to mutated products of gene editing, the concept of exemptions due to familiarity be broadened to include plants with transgenic traits that are familiar in type and inherently unlikely to give a significant advantage to wild plants. Examples would be sterility traits, stature reduction traits, and quality traits relevant to industrial processing (e.g., modified lignin in alfalfa and trees). According to the commenter, another class of strong candidates for plant kingdom-wide exemption are the widely used marker genes, such as nptII for kanamycin resistance, T-DNA borders, and widely used promoters such as 35S and NOS.

APHIS appreciates these comments. The commenter did not provide sufficient scientific evidence for the comments to be actionable at this time, however.

Several commenters asked that APHIS clarify the regulation of plants containing stacked traits. One commenter requested that APHIS codify in the regulations that plants developed through traditional breeding that are derived from products determined to not be regulated (either because of an exemption or as a result of an RSR) would themselves be unlikely to pose increased plant pest risk and therefore would not be subject to regulation. Other commenters argued that APHIS should assess the risks of stacked traits, particularly plants containing multiple herbicide resistance traits, using the noxious weed authority.

A discussion of our noxious weed authority in the context of these regulations is presented later in this document.

APHIS notes that in accordance with 340.1(c) the regulations under the part do not apply to GE plant-trait-mechanism of action combinations that have previously undergone an analysis

in accordance with § 340.4 and are not subject to the regulations. APHIS notes that the word, "combination" used in the regulation text is deliberately enumerated as singular and not plural. As such, the Agency anticipates that plants that are the genetically engineered product of more than one previously evaluated combination will be subject to evaluation under § 340.4.

Finally, several commenters requested clarity on the regulatory status of plant-trait-MOA combinations that were previously deregulated under part 340 or deemed to be not regulated under the "Am I Regulated" (AIR) process.

All plant-trait-MOA combinations that were considered nonregulated under the original regulations will have nonregulated status under the revised regulations as well. GE plants determined not to require regulation pursuant to the current AIR process would retain their nonregulated status under the new regulations to prevent potential market disruptions and provide regulatory certainty for developers. These plants would be listed separately from those evaluated at the MOA level at https://www.aphis.usda.gov/aphis/ourfocus/biotechnology, and this list of plants determined not to require regulation pursuant to the current AIR process could not be used by developers for determining the regulatory status of future products based on MOA in exemption § 340.1(c).

Self Determination.

Under the June 2019 proposed rule, developers would have the option to determine whether their modified plants belong to one of the categories listed under § 340.1(b) or (c) and are therefore exempt from the regulations. As stated in the preamble to that proposed rule, allowing for such "self-determinations" would provide developers with regulatory relief and open more efficient and predictable pathways for innovators to get new modified plants that do not require regulation to market, in turn supporting further innovation. Eliminating the need for

redundant evaluations of products would allow the Agency to devote more attention to assessing and regulating GE organisms that are likely to be associated with potential plant pest risks.

Commenters overwhelmingly opposed such "self-determination." Many cited potential risks that could result from allowing developers to determine whether their products are eligible for exemption from the regulations. Others questioned whether allowing developers to make such determinations would actually relieve regulatory burden and incentivize innovation to the extent that we anticipated. The comments are discussed in detail in the paragraphs that follow.

Many commenters opposed "self-determination" on the grounds that allowing developers to regulate themselves could result in conflicts of interest. It was stated that developers of GE products with a financial stake in the outcome should not be allowed to determine which products should be subject to regulatory review. Such an approach would fatally undermine the integrity, rigor, and credibility of what must be an independent regulatory process, weakening Agency ability to protect the public interest, and furthering mistrust in the US Federal regulatory system in the public's eye and among key trading partners. By avoiding the RSR or permitting process, the developer could get its new product to market without it ever having undergone an objective, third-party review. In allowing developers to determine whether their products are eligible for exemption, according to these commenters, we are effectively abdicating our regulatory authority and not carrying out our mission to protect U.S. agriculture.

We do not agree with these comments. The revised regulations in 7 CFR part 340 recognize that GE plant products that are the result of modifications that coincide with traditional plant breeding do not pose additional plant pest risk and should not be regulated under these regulations. Products that do not fall within the regulatory scope of 7 CFR part 340 have not

been subject to compulsory regulation in the past, and developers have always been able to act accordingly to determine whether their products are subject to the regulations. The provisions of this rule are consistent with past practices under this part.

It was further argued that allowing developers to determine the regulatory status of their products will result in less transparency and greater risk of commingling with organic and other non-GE crops and will damage consumer confidence. Allowing developers to determine the regulatory status of their products, it was claimed, will result in an overall loss of transparency in that the public would not have access to the data used by developers to make their determinations. Organic farmers would have less information about modified crops grown near their fields than they do now, since the information that informed developers' determinations will remain proprietary, and their ability to take preventive measures would be hindered. Some commenters cited the recent finding in Washington of unapproved GE glyphosate-resistant wheat as an example of the risks posed by allowing developers to determine whether their products are eligible for exemption and by reducing our regulatory oversight of GE products more broadly.

We do not agree with these comments. We anticipate that many developers whose products fall within an exemption will request confirmation letters. Those letters will be posted on the APHIS website and will be available to the general public, including organic and other growers of non-GE crops. Information from previous RSRs will also be available to the public.

In the preamble to the June 2019 proposed rule, we stated that a developer who made a determination that APHIS found not to be valid would be subject to remedial measures or penalties in accordance with the compliance and enforcement provisions contained in § 340.6 of the June 2019 proposed rule.

Some commenters stated that there is a need for a plan for detection and enforcement in cases where developers incorrectly determine their products to be non-regulated, or where changes in evidence may call a developer's determination into question. Without a record of what plants are being released, it will be impossible to conduct any kind of periodic surveillance or audit to ensure compliance. This difficulty may be partly addressed by having a compulsory reporting mechanism whereby a responsible party fills out a form to declare their modification and assert its exempt status. This would create a searchable record. While a database compiled from self-reported data would not offer complete protection against bad actors, when combined with penalties that are proportional to the degree of harm done by a developer incorrectly making a determination, it may aid in correcting incorrect determinations by developers.

APHIS acknowledges its ability to detect invalid determinations made by developers is limited. If a plant pest issue arises from a plant made with a modern plant breeding technique, detection might occur during an ensuing investigation. A similar issue exists under the current regulations: A developer could knowingly or unknowingly violate APHIS regulations by transporting, importing, or releasing into the environment a regulated plant without APHIS authorization.

If a determination made by a developer should be found to be invalid, however, APHIS does have the authority to enforce sanctions. As noted in the preamble to the June 2019 proposed rule, pursuant to sections 7714 and 7731 of the PPA, APHIS may seize, quarantine, treat, destroy, or apply other remedial measures to an organism covered under the regulations that is new to or not widely prevalent or distributed in the United States to prevent dissemination of the organism. Enforcement provisions are also included in § 340.6 of this rule. APHIS also

has many years of experience in initiating and coordinating enforcement action as appropriate, in cases where compliance issues exist.

Even in cases where we would impose penalties for invalid determinations by developers, some commenters expressed skepticism that those penalties would be efficacious in remediating harm or preventing further harm. If the movement or release of a GE product that had already reached the market based on a faulty determination by a developer resulted in commingling with other crops or the dissemination of plant pests, whatever penalties or remedial actions APHIS would impose, would likely neither prove adequate to address injuries to innocent parties nor provide sufficient disincentives to discourage bad actors from making invalid determinations. Elaborating on the latter point, one commenter stated that penalties imposed by APHIS after the fact may not even be legally defensible if we have allowed a developer to determine whether its product is eligible for exemption. Another commenter stated that APHIS, lacking a post-commercialization monitoring program, has little capacity to recall the products of invalid determinations by developers.

We do not agree with these comments. In the event APHIS discovers that a developer makes an invalid determination, the specific penalties and/or remedial action will be applied on a case by case basis as appropriate. Similarly, whether the discovery of an invalid determination is too late also depends on the particulars. In regard to legal defensibility, the PPA provides ample flexibility and broad civil penalty authority to deter violations of the PPA. For example, the PPA provides statutory maximum penalties of $1,000,000, for any person who willfully violates the PPA.

Other commenters feared that the penalties could be excessive. It was stated that any such penalty applied to a developer must be based on a demonstration of significant economic

harm to another entity from the error, and not technical or minor errors in interpretation. The commenters further stated that in such situations, the penalties must be proportional to that harm.

We agree that penalties must be proportional to the severity of violations and the harms that may result from them, and we will enforce the regulations accordingly. Congress has directed APHIS, via the PPA, as to the factors for consideration in assessing penalties under the PPA. These factors include "the nature, circumstance, extent, and gravity of the violation or violations," as well as the violator's ability to pay, the effect of the penalties on the violator's ability to continue to do business, and any history of prior violations.

In the preamble to the June 2019 proposed rule, we stated that one of the benefits of "self-determination" is that it would enable APHIS to focus its regulatory resources and risk analyses on unfamiliar products and thereby avoid conducting repetitive analyses on GE products that are very similar to those we have already evaluated for regulatory status. APHIS would thus be able to utilize its staff time more efficiently, and provide better stewardship of taxpayer dollars than it could under the existing regulations.

One commenter stated that our rationale does not hold up. The commenter viewed developer-made determinations as allowing APHIS to evade its regulatory responsibilities rather than enabling the Agency to use its resources more efficiently. The commenter stated that if GE developers are concerned about delays in getting their products to market because, in their view, APHIS does not have sufficient resources to conduct all reviews in a timely manner, then those developers should lobby Congress to provide more funding to enable APHIS to perform its duties in a more timely manner, as opposed to having the Agency reduce its oversight role.

APHIS disagrees with this comment. The plants that qualify for exemption under this part fall into two categories: They could otherwise have been developed through traditional breeding

techniques and have an acceptable level of risk that does not require regulation or they have the same plant-trait-MOA combination as other plants that have already been evaluated by APHIS and found to be not subject to the regulations. APHIS can utilize its resources most efficiently by focusing them on evaluating GE plants that do not fall into these categories and therefore may pose a level of risk that requires regulation. In addition, other plants exempted from regulation have already been evaluated previously by APHIS.

Many other commenters expressed skepticism about the efficacy of allowing developers to determine whether their products are eligible for exemption from an opposing perspective. These commenters doubted that such "self-determination" would provide the regulatory relief that we claimed in the preamble to the June 2019 proposed rule. One reason given was that most developers would seek certification or confirmation from APHIS that their determinations were valid, given the possible liabilities associated with making incorrect determinations. Such certification would therefore become a *de facto* requirement. One commenter expressed the concern that in order to receive such confirmation, developers would need to provide the information described in proposed § 340.4, which contains information requirements for RSRs. It was further suggested that while academics, startups, and small developers could see some benefit from "self-determination," companies with existing portfolios of GE crops will be in a better position to benefit.

We do not agree with these comments. If innovators choose to forgo the regulatory relief provisions offered by 7 CFR part 340 for any reason, they are welcome to do so. In this regulation, APHIS focuses on plant protection, while also easing regulatory burdens. As such, we also aim to be responsive to repeated concerns raised by small businesses, academic-based researchers, and other small-scale innovators who have reported past difficulty successfully

seeing products through to commercialization. The approach APHIS has taken is fully consistent with the priorities and direction provided by Executive Order 13874.

In § 340.1(d) of the June 2019 proposed rule, we indicated that developers may request confirmation from APHIS that the plant is not within the scope of the regulations in this part. A developer may find a confirmation letter useful in marketing its products domestically or overseas because the letter would serve as verification to an importing country or other party that APHIS concurs with the developer's determination. Confirmation is not required, however, and for developers not seeking confirmation letters, no submission of information to APHIS is required, nor is any response from APHIS. Guidelines for the information that would need to be submitted to enable APHIS to respond to a request for confirmation are discussed below.

Some commenters expressed doubt that developers would even be able to employ the "self-determination" option due to the lack of clarity surrounding it. It was stated that decisions on a product's regulatory status would be based on APHIS' assessment of plant pest risk, but because APHIS would define plant pest risk and because the Agency did not provide a list of traits for identification of a plant pest in the proposed rule, a developer would lack the guidance to make a determination safely.

APHIS disagrees with this comment. This rule clearly outlines the kinds of information needed to successfully navigate the APHIS regulatory system, as well as the protection goals and criteria that APHIS will consider as part of this process. Plants that clearly meet the exemptions listed under § 340.1 will not require regulatory oversight under 7 CFR part 340. The exemptions in § 340.1(b) are based not on the trait, but on whether the plant could have otherwise been produced through traditional plant breeding techniques. The exemption in § 340.1(c) is based on whether the plant-trait-MOA combination is the same as one that APHIS has previously

determined to be nonregulated. APHIS will publish a list of such combinations, which developers may use in determining whether their GE plant qualifies for exemption under § 340.1(c). As more GE plants undergo RSRs to determine their regulatory status, that list will grow. A list of traits for identification of a plant pest is not needed in order for developers to determine whether their product meets one of these exemptions in § 340.1(b) or (c).

Several commenters recommended that we provide more certainty about the process by issuing guidance documents to aid developers in making their determinations. Such documents, it was stated, could include, among other things, information requirements and timelines, including timelines for APHIS responses to requests for confirmation. Many commenters stated that, in general, defined timeframes for APHIS regulatory actions are important to improve predictability and support the planning needed to conduct seasonally based field research, and therefore should be included in the regulations. Most commenters who provided specific timeframes for confirmation requests suggested that APHIS should respond to such requests within 60 days. It was further suggested that to provide developers with additional guidance for making determinations, APHIS should maintain a database of products that have undergone RSRs and been found not to be subject to the regulations.

APHIS has had a longstanding practice of providing guidance to aid the regulated community in complying with the regulations. APHIS will provide guidance to developers on how to determine whether their product is exempt from these regulations as part of implementation of the final rule. We will also maintain on our website requests for and results of RSRs. That information will aid developers in making their determinations.

Regarding timeframes, in the preamble to the proposed rule, APHIS noted that we anticipate a timely turnaround time in providing confirmation letters. APHIS agrees that

providing a more specific timeframe for responses to confirmation requests would improve predictability. Based on our experience with the current Am I Regulated process, which is functionally similar to the confirmation process, APHIS has amended § 340.1(d) by adding a sentence indicating that, except in unforeseen circumstances, written responses will be provided within 120 days of receiving a confirmation request containing sufficient detail to determine whether the plant meets one of the exemptions in § 340.1.

One commenter stated that the type of information provided to the Agency by developers should be a description of the crop and the justification for meeting the exclusion, which would be similar to the information submitted for the "Am I Regulated" Process.

APHIS agrees with the sentiment expressed in this comment and is therefore setting out guidelines for parties requesting confirmations to submit to APHIS in support of their requests. The guidelines are listed below and will also be posted on the APHIS website at https://www.aphis.usda.gov/aphis/ourfocus/biotechnology. In addition, developers who have specific concerns may consult with APHIS.

In communications with APHIS requesting confirmation of exemption from the regulations, requesters will be expected to submit the following:

- A description of the plant, trait(s), and modification(s).
- A clear statement of which regulatory exemption the biotechnology developer is claiming for the plant and why the plant qualifies for that exemption.
- Details about the scientific method used to validate that the plant met the exemption criterion.

APHIS expects that the description of the plant will include both the scientific and common names. The trait information should include a description of the intended and any

observed phenotype(s) of the plant. Details about the modification(s) must provide APHIS with a clear understanding of the genetic change in the plant. In the case of § 340.1(c) exemptions, requesters must submit the MOA.

Many commenters advocated that we establish a mandatory process for developers to notify APHIS of their determinations and for APHIS to issue confirmations. Some commenters requested that confirmation be mandatory for all determinations made by developers, while others stated that confirmation should be mandatory only for developer-made determinations of products that will be commercialized. Many requested that the process be streamlined and include information and self-reporting requirements and timelines. It was recommended by some commenters that developers be required to provide notice to APHIS 90 days before putting a product on the market.

The confirmation process is voluntary, and APHIS notes that a "mandatory" confirmation and/or notification process would run counter to the spirit of regulatory relief offered in this rule. Commenters did not provide sufficient explanation or outline how developers of products that are not subject to the regulations could be compelled to comply with a requirement for mandatory participation in a confirmation process. APHIS notes, that even if the commenters had provided a sufficient regulatory mechanism to do so, a mandatory process would likely trigger the emergence of trade concerns, as products that are scientifically justified to be exempt would also appear on lists of GE articles–essentially creating a third category of products. APHIS further notes that a mandatory process would likely disadvantage the very small-scale, mid-size, and university researchers and innovators that the rule was intended to aide. Lastly, APHIS notes that the proposal for a mandatory confirmation provides no added benefit in plant protection, for which the rule is primarily purposed.

Some of the commenters who favored a formal or mandatory confirmation process did so because they questioned the utility of a voluntary process. It was stated that an APHIS confirmation that a determination made by a developer is valid, as provided for in the June 2019 proposed rule, will be a formulaic letter without an accompanying risk assessment. Some trading partners may not view such confirmation letters as sufficient to meet their own requirements for admission of U.S. GE products. It was stated that to keep export markets running smoothly, industry needs an official US attestation that the new traits do not pose a plant pest risk.

We do not agree with these comments. The confirmation letters will state that the product in question meets a regulatory exemption or has plant-trait-MOA combination that has already been reviewed by the Agency. APHIS currently works with, and is committed to continuing to work with, international trading partners and exporters to resolve trade concerns. International trade issues are discussed in greater detail later in this document.

Some commenters addressed the issue of whether, or how much, information pertaining to determinations made by developers and APHIS confirmations should be made public. Some commenters, citing the need for transparency and certainty, recommended that we post confirmation inquiries and confirmation letters on our website. Others, however, thought that such information should be treated as confidential business information (CBI) and therefore not be made publicly available. One commenter suggested that we use a process similar to that of the existing "Am I Regulated" process, under which CBI exemptions could be claimed in the request for confirmation submitted to APHIS, and a non-CBI version of the submission could be made publicly available.

In the interest of transparency, APHIS will post the confirmation letters online. APHIS notes, however, that confirmation letters are subject to claims of CBI and will proceed in

implementation in accordance with all applicable laws and procedures. Such procedures may include making the letters publicly available with CBI removed.

Finally, there were a few comments on proposed § 340.1 that did not fall into any of the categories discussed above.

One commenter suggested that the exemptions should focus on plant species, not variety, as well as the purpose and type of application of genome editing. The commenter stated that genome editing can both be used to produce or improve on a specific characteristic or phenotype, such as silencing a disease sensitive gene, and to improve existing breeding processes themselves, such as using gene editing to more efficiently induce double haploids.

The "purpose and type of application of genome editing" is just another way of describing the plant trait-MOA combination. Exemptions generally apply at the species level.

Another commenter thought that there was a possible conflict in between § 340.1(c) and § 340.2(a). The latter paragraph states that a plant with a plant-trait-MOA combination that has not been evaluated by APHIS for regulatory status in accordance with § 340.4 would have to move under permit. According to the commenter, the conflict arises because products we would allow to move without permits based on developers' determinations would not have been evaluated by APHIS.

We do not see such a conflict. When a developer determines that a GE plant falls under § 340.1(c), it is not subject to the regulations in part 340 and therefore does not require a permit for movement. We are making an editorial change to § 340.2(a), however, to clarify that a GE plant will be subject to the regulations if it has not undergone an RSR in accordance with § 340.4 or if it has undergone an RSR and, as a result of the evaluation, is subject to the regulations. Such GE plants will require permits for movement.

One commenter stated that by allowing developers to determine whether their products are eligible for exemption, we would not be in compliance with the requirement of the Cartagena Protocol that countries list all GE organisms released into the environment in the Biosafety Clearinghouse.

APHIS notes this comment, and wishes to clarify that the United States is not a signatory to the Cartagena Protocol. Many international efforts are underway to align regulatory approaches and seek compatibility for emerging technologies that were not envisioned or contemplated when existing policies were developed.

Two commenters requested that the Agency develop and issue guidance for developers of non-plant GE organisms to give them an opportunity to determine for themselves whether their products are subject to the regulations and to apply to the Agency for confirmation of regulatory status.

APHIS does not agree that such a process needs to be developed. Currently, the Agency responds to the developers' questions about whether a specific GE organism, including a non-plant organism, is subject to the regulations. The Agency will continue that practice after this final rule becomes effective. The proposed confirmation process is relevant to a developer determining that an exemption in § 340.1 applies.

Scope of the Regulations

Section 340.2 of the June 2019 proposed rule delineated the scope of the regulations. We proposed to regulate, i.e., require a permit for the movement of, any GE organism that:

- Is a plant that has a plant-trait-MOA combination that has not been subject to RSR; or
- Meets our proposed definition of a *plant pest*; or

- Is not a plant but has received deoxyribonucleic acid (DNA) from a plant pest, and the DNA from the donor organism either is capable of producing an infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease; or
- Is a microorganism used to control plant pests or an invertebrate predator or parasite (parasitoid) used to control invertebrate plant pests and could pose a plant pest risk.

Some commenters viewed a regulatory approach that provides for regulations of only those GE organisms that are plant pests or pose a plant pest risk as too narrow. Such an approach, it was stated, isolates the GE organism from the environment in which it is used and the process by which it is developed, thereby impeding science-based risk assessment. According to these commenters, other hazards potentially associated with GE organisms and not accounted for in the June 2019 proposed rule need to be addressed. These include the increased risk of commingling with non-GE crops; the potential for the creation of superweeds; pesticide overuse; habitat destruction; reductions in insect populations and increased herbicide use, which, according to the commenters, has been associated with GE crops and may have additional deleterious effects on the environment and on human health.

While we recognize the legitimacy of the commenters' concerns, many of these comments are outside the scope of this rulemaking and of our statutory authority under the PPA.

Some commenters questioned the scientific justifications for the above listed categories of GE organisms that would fall under the regulations. It was stated that APHIS needs to re-cast its entire proposal and frame it around the identification of the characteristics of the organism or phenotypes of concern for which a plausible case can be made, based not on speculation but data and experience, that they present an unreasonable risk to American agriculture. It was further

argued that there is no scientific justification for regulating by plant-trait-MOA instead of phenotype associated with the trait.

In order for the regulations under this part to enable future innovation while simultaneously protecting American agriculture from potential risks to plant health, it is vital that the regulations be prospective rather than retrospective. A regulation that enumerated phenotypes that the Agency is concerned with would become immediately obsolete upon issuance. As articulated clearly in numerous studies, including those by the NRC, no entity has the foresight to identify only those phenotypes that present concerns decades into the future. As such the Agency does not consider this approach to be feasible. Instead, the Agency has articulated a regulatory approach that is adaptable to future innovation and continues to protect against risk, even in cases where it is not possible to envision the kinds of products being developed in the future.

A commenter stated that the restriction in § 340.2(c) covering a non-plant GE organism that has received DNA from a plant pest is unclear and lacking in scientific justification. The commenter questioned whether receiving DNA from a plant pest would likely make the recipient into a plant pest.

The commenter misconstrues § 340.2(c), which states that non-plant GE organisms that receive DNA from a plant pest will be regulated if that DNA is capable of producing an infectious agent that causes plant disease or if the DNA encodes a compound that is capable of causing plant disease. Such non-plant GE organisms could pose a plant pest risk, justifying their regulation under this part.

Some commenters stated that organisms and microorganisms used to control plant pests should not require regulation if they are not plant pests themselves or do not pose a plant pest

risk. One commenter stated that there appears to be a conflict between § 340.2(d) and EPA's regulatory authority under the Federal Insecticide, Fungicide, and Rodenticide Act for microbial pesticides. The commenter further stated that the intent of the PPA for biocontrol organisms is to facilitate their development, but that APHIS is proposing to require additional regulatory requirements without indicating a need for these extra requirements in terms of protecting against plant pests.

We agree with the first comment, and this rulemaking does not provide for the regulation of such organisms. As we noted in the preamble to the June 2019 proposed rule, "GE non-plant organisms that do not pose a plant pest risk would not fall under the scope of the regulations and therefore would not require permits for movement." We disagree with the remaining comments. As we noted in the preamble to the proposed rule, while biological control organisms are generally not plant pests, their potential effects on organisms beneficial to agriculture could indirectly affect plant health. The PPA provides the authority to regulate such biological control organisms used to control plant pests to ensure they do not pose a plant pest risk. As with non-GE biological control organisms, the types of GE biological control organisms APHIS would regulate could pose a plant pest risk by lacking sufficient specificity for the target pest and thereby harming beneficial non-target organisms, such as other invertebrate predators or parasites (parasitoids), pollinators, or microbes that promote plant health. Because biological control organisms are almost always intended for eventual release into the environment, it is not sufficient for us only to consider their use in controlling their target plant pest. We must also take into consideration the indirect plant pest risks that the organism may pose due to harmful impacts on non-target organisms that are beneficial to agriculture (*e.g.*, harm to natural enemies of plant pests). If the GE organism is known to have harmful impacts on beneficial non-target

organisms, it is consistent with APHIS' authority under the PPA to prohibit or restrict its release. To the extent that we do not know whether a GE biological control organism is sufficiently specific to avoid harming beneficial non-target organisms, it is also prudent for us to place regulatory controls on the movement and release of the GE biological control organism until the impacts on beneficial non-target organisms and any resulting direct or indirect plant pest effects are better understood. In addition, we will exempt biological control organism-containing microbial pesticide products that are currently registered with EPA as a microbial pesticide product and that are not plant pests.

Definitions

In this final rule, we have revised the definition of *article* to provide greater clarity. The definition in the June 2019 proposed rule was drawn from that provided in the PPA. However, while the PPA indicates that an article may be an object that could harbor noxious weeds, upon review of the provisions of the proposed rule, we have determined that it is not appropriate to consider such an object an article under the revised regulations. The proposed definition could have been interpreted to suggest that APHIS would regulate a GE organism and require permits for its movement, solely based on its noxious weed potential. As discussed elsewhere in this document, however, this is inconsistent with APHIS' intent. The revised definition reads as follows: "[a]ny material or tangible object that could harbor plant pests."

A commenter stated that we need to define *environment*, since movement under permit includes release into the environment. *Environment* was defined in the proposed rule, however, and we are retaining that definition in this final rule.

In the June 2019 proposed rule, we defined environment as, "[a]ll the land, air, and water; and all living organisms in association with land, air, and water." We are retaining that definition in this final rule.

Numerous commenters stated that the proposed definition of *genetic engineering* requires greater clarity. Several commenters asked the Agency to clarify that "synthetic" nucleic acids, for the purposes of this regulation, are those that are non-naturally occurring. Some commenters requested that the Agency clarify what is meant by both "recombinant" and "synthetic" nucleic acids and cited the definitions and exemptions in the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules" (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf). One commenter stated that they understood the term "synthetic nucleic acid" to refer to a sequence that was created "new from scratch" and not a plant's nucleic acid sequence that was modified.

APHIS does not agree that the term "recombinant" requires further definition in these regulations. After nearly half a century of research and development involving recombinant nucleic acids, the term "recombinant nucleic acids" is well understood. The definition that APHIS proposed was based on the definition of "recombinant and synthetic nucleic acids" contained in Section I-B of the NIH Guidelines. Accordingly, by "synthetic" nucleic acids we mean nucleic acids that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules. Such nucleic acids are not limited to those that are non-naturally occurring. They could also include nucleic acids with sequences identical to those that are naturally occurring, but which have been synthesized or amplified rather than constructed by joining nucleic acid molecules (i.e., recombinant nucleic acids). APHIS agrees that greater

clarity regarding the term "synthetic" would provide developers and other stakeholders with a clearer picture of the products that are included within the scope of the regulations. Therefore, we are changing the definition of "genetic engineering" to "techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome." This change is consistent with the objectives of the Coordinated Framework in that it aligns our usage of the term "synthetic" with that of the NIH.

One commenter believes that the definition for *genetic engineering* should include changes to the epigenome.

APHIS does not agree. Epigenetic changes are caused by endogenous regulatory processes, such as DNA methylation and histone modifications through naturally occurring enzymes or by small naturally occurring RNA molecules. Epigenetic changes reflect an interaction of the genome with the environment that leads to changes in gene expression without changing the sequence of DNA. Epigenetic engineering differs from genetic engineering in that the former merely adjusts the innate potential of the genome of an existing organism whereas genetic engineering has the potential to create organisms that otherwise could not exist but for the technology.

Some commenters recommended that we add a definition of *genetically engineered organism* to provide greater clarity around which organisms would be regulated. The following language was a suggested definition: "An organism developed using genetic engineering, excluding those offspring that do not retain the genetic modification of the parent. For the purposes of this part, a plant will not be considered a genetically engineered organism if it meets any of the criteria outlined in § 340.1(b)(1)(3)."

We do not agree with this comment. Because we already have definitions for *genetic engineering* and for *organism*, adding one for *genetically engineered organism* would be redundant.

A couple of commenters stated that the proposed rule lacked a definition of *natural gene pool* and a discussion of its relevance in terms of safety.

The term was used in the regulatory text in § 340.1(b)(3). As discussed above, we have removed "natural" from that paragraph. The term "gene pool" is used in the paragraph in the manner in which it is commonly understood.

One commenter viewed our proposed definition of *person* as potentially problematic in that it could open APHIS to legal challenges. The commenter expressed concern that because the definition includes not only individuals, business entities, and associations but also any other "organized group," the argument could be made that APHIS falls under the definition. If so, according to the commenter, there might be the possibility of a conflict if decisions under these regulations are taken by the Administrator of APHIS. The commenter requested clarification on this issue.

The definition of *person* would apply to individuals or entities regulated by APHIS including the Agency. Under the law, a company is an entity that is recognized as a legal person that exists independently, with rights and liabilities. APHIS has, in the past, issued itself permits in conjunction with enforcement of the regulations so that the plant products could move legally across state lines. Therefore, regulation by APHIS under part 340 will not create conflict or otherwise be impacted.

A commenter stated that the proposed definition of *plant pest* is too broad and could be construed to cover model organisms, such as *Drosophila melanogaster,* that do not have

significant negative effects on agriculture. The commenter stated that an overly broad definition is of concern to biomedical researchers because some invertebrates they use could be classified as plant pests. Noting the lack of a mechanism to acknowledge that an organism that consumes plant material is not detrimental to agriculture, the commenter recommended that APHIS establish a mechanism for classifying an organism as "agriculturally unimportant within the plant pest category" and that such a classification have influence on APHIS' regulatory processes.

APHIS appreciates the comment. The definition of *plant pest* is based directly on, and does not exceed, the definition of the term in the PPA. The proposed regulations contained an exemption from the requirement for permit for interstate movement for *Arabidopsis thaliana*. In this final rule, we are adding an exemption from some permitting requirements for GE *Drosophila melanogaster*, which we will discuss in more detail below.

Another commenter stated that by adopting a definition of *plant pest* that aligns with the definition provided in the PPA, APHIS would regulate a broad range of GE animals, including those used in medical research, thereby imposing large, new, and unwarranted regulatory burdens on researchers in medical research and other fields.

APHIS disagrees with the comment. As we stated in the preamble to the proposed rule, while the PPA gives APHIS authority to regulate any nonhuman animal as a plant pest, it is longstanding APHIS policy not to regulate vertebrate animals as plant pests. In the absence of such a policy, all herbivores and omnivores could be considered plant pests, and thus subject to regulation, an untenable position since this would require APHIS to consider livestock, such as cows, sheep, and horses, as well as many laboratory research animals to be plant pests.

In the June 2019 proposed rule, we defined *plant pest risk* as "[t]he possibility of harm to plants resulting from introducing or disseminating a plant pest or exacerbating the impact of a

plant pest." Many commenters viewed the proposed definition as vague and potentially problematic due to the terminology we used.

Commenters expressed concern that the words "possibility of" in the proposed definition are vague and uncharacteristic of standard risk assessment terminology and methodology, which characterizes risk as either a likely or probable adverse outcome. Commenters also expressed concern that the word "harm" in the proposed definition is inconsistent with the PPA, and that the regulatory end-point should be risk of causing injury to, damage to, or disease in any plant or plant product. It was stated that the inconsistency and lack of precision in the terminology used in proposed definition could leave risk-based decisions made by APHIS open to challenge for not addressing all possibilities for harm, no matter how unlikely.

APHIS agrees with the commenters that greater clarity and consistency in the definition of *plant pest risk* would be useful and is revising it accordingly. We agree that the words "possibility of" are too non-specific. Numerous possible scenarios could be put forward as the basis for events that represent risk without any plausible basis for concluding that such scenarios could occur. The glossary of Society for Risk Analysis, which is available at https://www.sra.org/sites/default/files/pdf/SRA_glossary_20150622.pdf, defines *risk* as, among other things, "the potential for realization of unwanted, negative consequences of an event." We view this terminology as more precise than "possibility of" and are revising our definition of *plant pest risk* accordingly. We are also revising the definition to refer to the types of harms specified in the PPA. Accordingly, this final rule defines *plant pest risk* as "[t]he potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest."

Importantly, while APHIS defines *plant pest risk* in this rule in reference to the potential for direct or indirect injury, damage or disease, the RSR process itself is based on standard risk assessment practices and methodology that focuses on likelihood and magnitude assessment of *plausible* risks. Since the RSR process will require that a plausible risk be identified in order to proceed with further risk assessment, it will not be an open-ended evaluation of any possible scenario that could be imagined.

One commenter stated that plant-*trait-MOA is* not defined as a combination, though the individual terms are. If the combination has its own meaning, APHIS should clarify that.

Plant-trait-MOA does not have its own meaning. It refers to three individual terms/factors for analyzing whether certain GE organisms may present a plausible path way to plant pest risk and by which we determine whether a product actually poses a plant pest risk.

Under the definition of *responsible person* in the June 2019 proposed rule, responsibility for maintaining control over a GE organism under permit during its movement and assuring compliance with all permitting conditions could be given to an individual or an institution. A commenter stated that individuals should not be included under the definition. According to the commenter, responsibility should reside only with the institution with which the signatory or any other individual bearing such responsibility is affiliated. The commenter pointed out that staff often move among jobs well before permit conditions are fulfilled.

As discussed in the preamble to the June 2019 proposed rule, attributing responsibility for a GE organism moved under permit only to an institution may be problematic for enforcement of the regulations, because such responsibility can be diffused, resulting in no individual being held accountable for violations. Our definition ensures that some individual or party would be held accountable for violating permit conditions and/or regulatory requirements. If a responsible

person moves to a different job or otherwise leaves an institution, responsibility for any permits can be officially transferred to another qualified individual.

A commenter stated that there is no justification for the requirement contained in the proposed definitions of both *agent* and *responsible person* that they be legal U.S. residents and no means of verifying that they are.

We are retaining the proposed rule definition as it would be the strongest mechanism for ensuring accountability in the regulatory program. We have learned through administration of the program that the existing definition is not adequate, and has not provided the necessary framework to hold noncompliant developers responsible (e.g., academic researchers who returned to their native countries without taking steps to destroy their GE-test material prior to departure).

Finally, we have revised the definition of *State* to read as follows: "[a]ny of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territories or possession of the United States." This definition aligns with that contained in the PPA.

Regulatory Status Review

Section 340.4 of the June 2019 proposed rule set out the RSR process, under which developers may request that APHIS evaluate their novel plants and determine whether or not they fall within the scope of the regulations, i.e., under one or more of the categories in § 340.2. The section contained requirements for submitting requests for reviews and re-reviews, including supporting information; listed the factors APHIS will consider in the course of its reviews;

described the review process; and provided for public notice of RSR determinations. Commenters addressed all these topics.

As noted in the preamble to the June 2019 proposed rule, the RSR process applies only to GE plants. APHIS specifically solicited comments on whether the scope of the RSR should be expanded to include non-plant GE organisms as well as GE plants, whether some equivalent process for evaluating such organisms for regulatory status should be developed instead, and, if so, what factors the Agency should consider in its analyses.

Several commenters did request that APHIS develop a process to evaluate the regulatory status of non-plant GE organisms, based on the subject organism's potential plant pest risk; however, the commenters did not provide specifics on what factors the Agency should consider in its analyses. APHIS believes that further discussion and outreach with impacted developers and other stakeholders on this issue is required before pursuing rulemaking.

Some commenters stated that plant-made industrials and pharmaceuticals (PMPIs) should be eligible for RSRs in addition to GE plants.

As discussed in greater detail later in this document, under the present rulemaking, developers of PMPIs could request RSRs for their products.

We received several comments pertaining to the re-review process. Some commenters stressed the need to consider whether our requirements adequately address the risk of requests for spurious reviews. Noting that we proposed to require that any request for a re-review be supported by "new, scientifically valid evidence bearing on plant pest risk," commenters urged us to clarify what we mean by "scientifically valid evidence" in order to ensure that trivial evidence or conjecture, or publications in the numerous non-credible online "scientific" journals that have proliferated in recent years, cannot form the basis of a request. Clarification was also

requested as to whether re-reviews can be initiated for all products for which RSRs have been completed or only for those found after an initial RSR to be subject to the part 340 regulations. One commenter stated that in cases of re-reviews initiated by APHIS, the Agency needed to provide for due process by allowing developers adequate time to respond.

APHIS agrees that requests for re-review must be based on "scientifically valid evidence" that relates to plant pest risk. APHIS has experience dealing with such requests and will conduct an objective analysis of re-review requests to determine whether re-reviews are warranted. A valid re-review request would apply only to those GE plants or plants products that were previously found to be subject to the regulations after an initial RSR was conducted. In the June 2019 proposed rule, § 340.4(a)(4) specified information requirements for persons submitting a request for the Agency to conduct an RSR of a GE plant and stated that additional guidance on how to meet the requirements would be found on the APHIS website. A few commenters requested that APHIS either incorporate the additional guidance into the regulations, commit not to change the guidance without public notice and comment procedures, or make clear that the additional guidance is non-binding since any changes made to it would not otherwise be subject to formal notice and comment.

After reviewing these comments, APHIS has decided to pursue the second of the three recommended options. When APHIS seeks to make a substantive change to the information provided on our website, we will indicate the proposed change, provide an explanation for it, and take public comment on it. We will then review the comments and make a determination as to whether to implement the change. In this final rule, we are revising § 340.4 to incorporate the notice and comment process. The revised § 340.4 also uses the term "detailed information" rather than "guidance," which was used in the proposed rule. We are making this change, which

we have placed in a new paragraph (a)(4)(iv), to clarify that in order to satisfy the broad requirements contained in the regulations for information on the comparator plant, the genotype of the modified plant, and the new trait(s) of the modified plant, the developer must provide the detailed information indicated on the website. We anticipate that this change will provide more consistency and predictability regarding information requirements than we did in the June 2019 proposed rule. Such predictability is important for ensuring that developers can adequately comply with the regulations and plan their product development activities accordingly.

A number of commenters expressed concerns about specific details of how to meet the detailed information requirements for the RSR process that will be maintained on APHIS website. Some commenters were concerned that the requirement for information on the genotype of the modified plant was unclear and could be interpreted as requiring sequence information comparing the entire genome of the modified plant to that of the unmodified plant. Commenters stated that sequence information should be limited to sequence information for the specific genetic modification(s) in the plant. One commenter noted that some gene-edited products could have had genetic material inserted during development that was subsequently segregated away, and that we could clarify that the whole genome sequence information is not required by specifying that the required sequence information pertains to the targeted modified sequence.

APHIS agrees with these comments. It was not our intent to request whole genome sequence information. Rather, we are requesting sequence information on the specific targeted genetic modification(s) in the plant. We have revised the information that will be published on the APHIS website to clarify the sequence information that must be provided.

Some commenters stated that sequence information is not needed to determine if a GE plant poses a plant pest risk as long as developers provide the type of modification and describe the genotype by providing information on the insertion, deletion, and/or expressed gene product, and that if sequence information is required, it be limited only to sequences that confer the trait(s) and should exclude vector sequences that are not in the final plant.

APHIS largely disagrees with these comments. The specified sequence information is needed by APHIS in order to confirm the intended trait(s) at the molecular/genetic level, understand the MOA in order to understand the plant pest impact(s), if any, of the modification(s), and assess similarity with previously reviewed GE plants. For inserted genetic material, APHIS requires the sequence of the entire insert for molecular characterization. All genetic elements integrated into the plant genome need to be described; therefore, vector sequence information is not required if vector sequences are not inserted. For gene editing, the sequence of the entire edited gene or functional motif of a regulatory region (e.g., a transcription factor binding site in a promoter region) is required to understand the targeted sequence modification(s). The characteristics imparted by inserted or edited regulatory sequences (such as expression levels, patterns, timing, etc.) are necessary to verify the full extent of the engineered genetic changes as part of understanding the plant pest risk associated with modification(s).

Commenters raised concerns about how to meet the information requirements concerning the MOA. One commenter stated that while there may be information on a specific gene product, the precise mechanism of action may not be elucidated.

APHIS recognizes that the MOA may not always be well characterized. As we indicated in the preamble to the June 2019 proposed rule, we are requiring information on the MOA to the extent that it is known. We have revised the detailed information provided on the APHIS website to clarify this point.

Other commenters stated that certain information categories appear to exceed what APHIS has historically asked for when reviewing petitions for nonregulated status under the current regulations, and that RSR information requirements should align with the information the Agency has required previously, should not increase a developer's data submission burden, and should be sufficiently flexible to accommodate the nature of the particular product being evaluated. A commenter stated that gene expression data is unnecessary in many cases and that APHIS should clarify when it would be required, such as when the intent is to change the expression pattern of a gene. Another commenter stated that information on the production, creation, or enhancement of a reservoir for a plant pest goes beyond the type of information currently submitted by developers in support of petitions for nonregulated status.

APHIS largely disagrees with these comments but recognizes that the preamble to the June 2019 proposed rule lacked sufficient clarity regarding information requirements that apply at various stages of the regulatory status review process. The information developers must submit, as specified in § 340.4(a) of this final rule and on the APHIS website, generally aligns with information the Agency has been seeking previously, will reduce rather than increase a developer's data submission burden, and is intended to be sufficiently flexible to accommodate the nature of the plant being evaluated. Under the petition process, developers have had to submit data and information regarding a broad range of potential harms for evaluation by APHIS, regardless of whether the plant could plausibly pose a plant pest risk. The regulatory

status review process differs from the petition process in that the Agency is requesting much less information for the initial review, with no requirement for laboratory or field test data. If the Agency is unable to identify a plausible pathway by which the GE plant could pose an increased plant pest risk in the initial review, developers will not be required to submit any additional information to APHIS. When there is a plausible pathway to plant pest risk identified, developers will receive feedback about the type(s) of information APHIS would need to complete a plant pest risk assessment early in the RSR process. This information would focus on that required to assess the identified plausible pathway. The preamble to the proposed rule discussed some of the types of information that might be required in this situation, but incorrectly made it appear as if this information would be required for all initial reviews. We now clarify that such information could be submitted during the initial review stage, but submission would be optional. We are revising the detailed information that will be published on the APHIS website to make this distinction clear.

As noted, when there is a plausible pathway to plant pest risk identified in the initial review, developers will receive feedback about the type(s) of information APHIS would need to complete a plant pest risk assessment early in the RSR process. Under both the current petition process and in the proposed rule, APHIS may ask for information, such as any changes in the presence or level of plant pests in field trials, when there is a scientifically plausible hypothesis that the GE trait can result in a change in plant pest risk. As indicated in the preamble to the June 2019 proposed rule, the provisions specifying information requirements for regulatory status review would not preclude APHIS from asking for field-test data or other information if APHIS considered it necessary in order to conclude review of a particular request. APHIS would ask for gene expression data or other data relevant to assessing whether the GE plant

could have increased importance as a host for plant pests only when such a plausible pathway to plant pest risk is identified during the initial review. APHIS has clarified that additional data would be requested on the basis of identified plausible pathways to plant pest risk by adding to the existing text in § 340.4(b)(3)(i) the following: "APHIS may request additional information as needed to evaluate the factor(s) of concern."

One commenter found it difficult to understand how plant-trait-MOA could be adequately evaluated without field trials.

Data from field trials does not provide information about the plant-trait-MOA. As we noted in the preamble to the proposed rule, APHIS' experience in preparing risk assessments in accordance with the petition process indicates that field trial data is generally not necessary unless it addresses an identifiable plausible pathway to plant pest risk. The introduced trait and MOA provide the most reliable indicators of the organism's potential for plant pest risk. As we also noted in the June 2019 preamble, our conclusions are consistent with findings of reports of NAS.[7, 8]

By having an understanding of the biology and any existing impacts of the plant, the genetic trait to be inserted into the plant, and the MOA, APHIS is able to conduct a review based upon the large body of scientific publications, knowledge and experience. Information from field tests would be unnecessary, in most cases, for a determination of regulatory status under these regulations. Accordingly, field test information would not be a generally applicable

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[7] NRC. 1989. *Field Testing Genetically Modified Organisms: Framework for Decisions*. Washington, DC: National Academy Press.

[8] National Academies of Sciences, Engineering, and Medicine. 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC: The National Academies Press. doi: 10.17226/23395.

requirement for the initial RSR and would only be requested as needed when further analysis is required. This approach would not preclude developers from providing information from field test they consider pertinent to our analysis. For example, if a developer requested a reevaluation of a GE plant that APHIS had previously considered to be subject to regulation, field test information demonstrating a lack of plant pest risk could be provided in support of that request. Nor would the provisions preclude APHIS from asking for field test information if APHIS considers it necessary in order to conclude review of a particular request.

The revised detailed information requirements that will appear on the APHIS website are listed below.

I. A description of the comparator plant, to include common name(s), genus, species, and any relevant subspecies information that would distinguish the plant;

II. The genotype of the modified plant, including a detailed description of the differences in genotype between the modified and unmodified plant, specifically:

   a. If genetic material is inserted into the genome, provide information on all inserted genetic material, including:

      i. For genetic sequences, the name of the sequence, the donor organism(s) or source, the function of the sequence, the nucleotide sequence, and if applicable, the publicly available sequence identification, protein accession number, and enzyme commission number. If inserted genetic sequences have been modified (e.g., codon usage efficiency, gene shuffling, etc.), a statement regarding the nature and purpose of the modification, and identification of the modifications by submitting an alignment of the modified sequence with the unmodified sequence.

ii. For regulatory sequences, the function of each regulatory sequence as it relates to the gene sequence and the donor organism(s) or source of each regulatory sequence. Identify promoters as constitutive, inducible, developmental, or tissue specific. If developmental/tissue specific, describe the stage(s)/tissue(s) at/in which the promotor is intended to be active.

b. If genetic material is not inserted into, or was inserted and is no longer present in, the genome, and the genome is modified in a way that does not fall under the exemptions in §340.1(b), provide:

i. The nature of the modification(s) and the gene(s) and function(s) being modified

ii. For substituted based pairs, the number of substitutions

iii. The original unmodified sequence aligned to the targeted modified sequence

III. A detailed description of the new trait(s) of the modified plant, including:

a. The purpose and intended phenotype of the new trait and available information on the MOA by which the intended trait is conferred;

b. Any expected changes in metabolism, physiology, and development due to the trait/genetic modification, to the extent known;

c. Optional: Any additional experimental data, publications, and other science-based assessments that may be helpful for APHIS' evaluation of the potential of the plant to pose plant pest risks. Such information could include, to the extent that it is known, information about any new enzymes or other gene products

produced; where, when, and at what level the introduced or modified genetic material is expressed in the plant; the biochemical action of the genetic material or its product; and how the genetic material or its product participates in or interacts with metabolic, physiological, or developmental processes in the engineered plant or in other organisms. (APHIS does not intend for submitters to generate experimental data specifically for a RSR. However, if a submitter is aware of information or experimental data in the public domain that may support our assessment, he or she may include it.)

The June 2019 proposed rule specified, in § 340.4(b)(1)(i) through (b)(1)(iii), the factors that APHIS would consider when conducting an initial review of the plant pest risk posed by the GE plant and any sexually compatible relatives that could acquire the engineered trait, relative to that posed by their respective non-GE or other appropriate comparator(s). To provide context for the discussion that follows, we are listing those factors below, as they appeared in the proposed rule.

I. The biology of the comparator plant and its sexually compatible relatives;

II. The trait and mechanism-of-action of the modification(s); and

III. The effect of the trait and mechanism-of-action on:

a. The distribution, density, or development of the plant and its sexually compatible relatives;

b. The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;

c. Harm to non-target organisms beneficial to agriculture; and

d. The weedy impacts of the plant and its sexually compatible relatives.

Commenters had concerns and questions about some of the factors. One commenter stated that APHIS should clarify that a comparator could be a GE plant, even though Codex Food Safety Guidelines do not allow a GE crop to be a comparator, since the majority of certain crops, such as corn and soybean, are already GE.

APHIS agrees that in some circumstances a GE plant could be an appropriate comparator and notes that the Codex Guidelines state that an appropriate comparator, ideally a near-isogenic parental line should be used. This does not preclude the use of a GE plant as a comparator when appropriate.

One commenter requested that APHIS define how it intends to determine "distribution, density, or development of the plant and its sexually compatible relatives and weediness across plant types." Another suggested that we add a definition of *weediness* since it is mentioned in the context of the RSR.

APHIS is making no changes to the rule in response to these comments. The plant pest risk assessment framework document that accompanied the proposed rule described how the distribution (including density) of the GE plant and its sexually compatible relatives can be predicted by the biological properties of the plant compared to the known distribution and properties of the comparator, in the context of the receiving environment. The development of the GE plant and its sexually compatible relatives can similarly be predicted. Assessment of these factors is important for determining if the GE trait(s) could increase the prevalence or alter the distribution of the plant or its sexually compatible relative(s) in such a way that they could have increased importance as hosts for plant pests. Consideration of those factors, along with any plausible changes in weedy impacts, will indicate whether the GE trait could change the potential of the GE plant or a sexually compatible relative to be a truly troublesome and

impactful weed, such that we would need to consider whether the GE plant should be considered for regulation pursuant to our statutory authority and the regulations issued under that authority. It is also important to point out that consideration of weediness has been a part of the plant pest risk assessments conducted in response to petitions for nonregulated status since the 1990s. This rule does not change this analysis.

Some commenters had concerns about the factor "harm to non-target organisms beneficial to agriculture," and asked us to shift our focus to adverse effect on trophic functional groups beneficial to agriculture and to articulate a scientific rationale as to how a plant, whether GE or not, could pose a plant pest risk on the basis of it harming an insect predator or pollinator.

Beneficial organisms such as predators and pollinators fall squarely under APHIS' authority because predators and pollinators are essential to plant health, and harm to these organisms may result in greater injury or damage to plants. APHIS disagrees with the suggestion to shift the focus to harm to trophic functional groups. Non-target organisms beneficial to agriculture encompass a broad range of organisms that provide ecosystem services. Focusing on certain trophic guilds is not adequate to address all aspects of plant pest risk to these organisms. For example, some GE traits may have greater effects on closely related groups of insects, regardless of the trophic guild of members of that group. When there is a scientifically plausible link to harm to non-target organisms beneficial to agriculture, the information needed for a plant pest risk analysis would be determined on a case-by-case basis, accounting for the particular biology of the GE plant, the MOA of the GE trait, and the environment.

In addition to listing the factors discussed above, proposed § 340.4(b) set out the components of the RSR process, including that of making determinations and providing public notice of them. Proposed paragraph (b)(1) stated that when APHIS receives a request for an

RSR, the Agency will conduct an initial review of the potential plant pest risk posed by the GE plant and any sexually compatible relatives that could acquire the engineered trait, relative to that of the plant pest risk posed by their respective non-GE or other appropriate comparator(s), based on the factors discussed above. Proposed (b)(2) stated that if the Agency is unable to identify potential plant pest risks in the initial review, the GE plant will not be subject to the regulations. Proposed (b)(3)(i) stated that if the Agency does identify potential plant pest risks in the initial review, APHIS will conduct an evaluation of the factor(s) of concern to determine the likelihood and consequence of the potential plant pest risk posed by the GE plant. Proposed paragraph (b)(3)(iii) stated that if the GE plant is found unlikely to pose a plant pest risk and, therefore, not to require regulation under this part, APHIS will post the finding on its website. Proposed paragraph (b)(3)(iv) stated that if APHIS is unable to find the GE plant unlikely to pose a pest risk, it will require regulation and its movement will be allowed only under permit in accordance with § 340.5.

Commenters expressed numerous concerns about this process. Some thought we provided insufficient detail, especially concerning the distinction between the initial review and the additional evaluation some GE plants would need to undergo. Others took issue with some of terminology we used, stating that it lacked clarity and therefore could lead to confusion about our regulatory focus and decisionmaking process. Numerous commenters proposed alternative language, in some cases arguing that their proposed alternatives were more consistent with standard risk assessment terminology and the PPA than what we proposed. It was also stated that our decisionmaking criteria should incorporate the concept that the plant pest risk posed by the GE plant should be greater than that posed by the plant from which it was derived in order for regulation to be appropriate.

APHIS agrees with many of these comments. In this final rule, we have amended § 340.4(b) to provide additional detail and clarity and to incorporate the concept that the plant pest risk posed by the GE plant or its sexually compatible relatives must pose an increased plant pest risk relative to the comparator(s) in order for regulation to be appropriate.

Regarding terminology, we have revised § 340.4(b) to indicate that in the initial reviews, we will make determinations on whether further review is necessary based on a finding of "plausible," rather than "potential," plant pest risks. We view the former term as more precise and more in keeping with standard risk assessment terminology. Further, since the RSR process will require that a plausible risk be identified in order to proceed with further risk assessment, the revision will ensure that the initial review will not be an open-ended evaluation of any possible scenario that could be imagined.

As noted earlier in this document, in connection with the discussion on confirmation letters, some commenters saw a need for timeframes for APHIS regulatory processes for purpose of predictability and business planning. Commenters raised the issue in connection with the RSR as well. We agree with the commenters on the need for timeframes and are adding them to paragraphs (b)(2) and (b)(3), as discussed below.

Revised paragraph (b)(1) contains provisions related to the initial review. The introductory text states that when APHIS receives a request for an RSR of a GE plant, the Agency will conduct an initial review to determine whether there is any plausible pathway by which the GE plant, or any sexually compatible relatives that can acquire the engineered trait from the GE plant, could pose an increased plant pest risk relative to the plant pest risk posed by the respective non-GE or other appropriate comparator(s), based on the factors listed in

paragraphs (b)(1)(i) through (iii) (also listed above), which remain the same as those in the proposed rule.

Revised paragraph (b)(2) states that APHIS will complete the initial review within 180 days of receiving a request that meets the requirements specified in this section, except in unforeseen circumstances. If the Agency does not identify a plausible pathway by which the GE plant or its sexually compatible relatives could pose an increased plant pest risk relative to the comparator(s) in the initial review, the GE plant will not be subject to the regulations. APHIS will post information on the plant and trait and a general description of the MOA on its website.

Regarding the timeline, while the RSR is a new process to APHIS, the initial review has some similarities to the current "Am I Regulated" process and, in many cases, may be completed rapidly. However, for plants that APHIS has infrequently authorized in the past, we anticipate that additional time will be required to compile information on the appropriate comparator(s) needed to conduct the initial review. In addition, we anticipate that additional time will be required to compile the information on new or more complex MOAs needed to conduct initial reviews. Based on our experience, we anticipate that we will generally be able to complete such reviews within 180 days, barring unforeseen circumstances.

Revised paragraph (b)(3)(i) states that if the Agency does identify a plausible pathway by which the GE plant or its sexually compatible relatives could pose an increased plant pest risk relative to the comparator(s) in the initial review, the requestor may apply for a permit and/or request that APHIS conduct an evaluation of the factor(s) of concern to determine the likelihood and consequence of the increased plant pest risk.

Revised paragraph (b)(3)(ii) states that for those GE plants for which such an evaluation is conducted, APHIS will publish the results of the evaluation in the *Federal Register* and will solicit and review comments from the public. Except in circumstances that could not reasonably have been anticipated, APHIS will complete these steps within 15 months of receiving a request for an RSR that meets our requirements. This evaluation will be similar to the current petition process, and will include, in addition to public notice and comment, preparation of any applicable National Environmental Policy Act (NEPA) analysis prior to decisionmaking; hence, the longer timeline.

Revised paragraph (b)(3)(iii) states that if APHIS finds that the GE plant and its sexually compatible relatives are unlikely to pose an increased plant pest risk relative to their comparator(s), the GE plant is not subject to this part and APHIS will announce the final determination in a subsequent *Federal Register* notice, and post the finding on its website. If APHIS does not make such a finding, the GE plant will remain regulated, and its movement will be allowed only under permit in accordance with § 340.5.

Due to the changes made in paragraphs (b)(2) and (b)(3)(iii), we are deleting proposed paragraph (c), as it is no longer necessary.

APHIS does not agree with other changes to the regulatory text suggested by some commenters. Specifically, the commenters recommended that we predicate our decisionmaking on whether the GE plant poses an "unacceptable plant pest risk" or an "unacceptable" or "unreasonable" "increase in plant pest risk."

APHIS appreciates these comments and has given them full consideration. APHIS does not find these terms to provide the necessary precision to become the foundation for regulatory analysis and decision making. For example, these terms could be interpreted to take into account

normative values and, if used as a regulatory benchmark, could place APHIS risk assessors in the position of deemphasizing scientific analytics. As such, APHIS does not make changes to the regulatory text under this part as suggested by the commenters.

A commenter stated that just as the MOA for achieving a phenotypic trait in a GE organism should be taken into account, the MOA for achieving the genotype changes used to achieve those phenotypic traits should be taken into account as well. According to the commenter, the reason APHIS regulations have been "event-specific" is because genetic material is inserted into recipient plants in an essentially random manner during the genetic engineering process which can create mutations in recipients at rates of ~30-60 percent, and uncharacterized genetic material/DNA can unintentionally become incorporated into recipients about 20 percent of the time.

We do not agree with this comment. As noted above, we have not seen evidence in the scientific literature that there are unique hazards that arise solely from the use of recombinant DNA techniques.

One commenter stated that putting RSR results on the web would encourage copycats rather than innovators.

We do not agree with this comment. As discussed later in this document, certain sensitive RSR information will be eligible for CBI exemptions and, therefore, protected.

Permits

Paragraphs (a) and (b) of proposed § 340.5 contained, respectively, permit issuing and application requirements. Proposed § 340.5(f) contained requirements for APHIS review of permit applications.

In the June 2019 proposed rule, APHIS proposed to remove timeframes for review of permit applications so as to ensure that the Agency has the appropriate time to evaluate each permit application based upon the plant pest risk posed by the GE organism and the complexity of the application. Some commenters opposed the change and requested that we retain those requirements in the regulations or otherwise incorporate into this final rule "reasonable" timeframes to provide greater certainty for developers about the length of the process. Commenters had various suggestions as to the length of the timeframe(s). One commenter, for example, recommended that APHIS be allowed 10 days to review applications for permits for interstate movement and 30 days for release permit applications. It was also recommended that we establish timeframes for making determinations on permit amendments and for review and comment by State and Tribal officials on permit applications.

Although we recognize the need for certainty about the length of the process, our experience has been that some permit and notification applications take a minimal amount of time and others take longer, and we anticipate this to continue. A review of our experience over the last 2 years demonstrates that 45 days is currently sufficient to authorize import and interstate movement permits, while up to 120 days are often needed to authorize release permits. Therefore, APHIS is adding a new § 340.5(g)(5)[9] containing timeframes for review of permit applications. New paragraph (g)(5)(i) states that interstate movement and import permits will be approved or denied within 45 days of receipt of a complete permit application, except in unforeseen circumstances. New paragraph (g)(5)(ii) states that release permits will be approved

[9] As explained below, we are adding a new paragraph (e) to § 340.5. As a result, paragraphs (f) through (k) of the June 2019 proposed rule are designated in this final rule as paragraphs (g) through (l). Except where otherwise indicated by a specific reference to the proposed rule, for purposes of this discussion, paragraphs will be referred to by their designation in the regulatory text of this final rule.

or denied within 120 days of receipt of a complete permit application, except in unforeseen circumstances. In cases where an environmental assessment or environmental impact statement is necessary to issue the permit, the 120-day period will be extended.

Paragraph (g)(3) of § 340.5 contains requirements for inspections related to permitted activities. The paragraph states that all premises associated with the permit are subject to inspection before and after permit issuance, and all materials associated with the movement are subject to sampling after permit issuance. In addition, the responsible person and agents must provide inspectors access to premises, facilities, release locations, storage areas, waypoints, materials, equipment, means of conveyance, documents, and records related to the movement of organisms permitted under this part.

A commenter stated that APHIS should define waypoint in a manner that accounts for the fact that applicants for permits may not be able to legally guarantee access to all waypoints, such as those that may be the sole property of a third-party shipping company.

APHIS will work with the permit holder if there is need to gain access to a waypoint not under their control.

In § 340.5, paragraph (g)(3), APHIS mandates that all materials associated with activities conducted under permit would be subject to sampling. One commenter questioned the need to include this requirement in the regulations. According to the commenter, the PPA gives the Agency authority to conduct investigations, including sampling, when required. The commenter stated that sampling has never been done outside the scope of an investigation, and that practice should remain. The commenter said that if APHIS decides to move forward within inclusion of a sampling requirement, it should clearly describe how those samples will be handled, the level of confidentiality that they will be subject to and the specific uses for which samples may be

taken in order to protect confidential business information. The commenter further stated that such samples are of proprietary research materials and valuable enough to be targets of misappropriation if not handled appropriately.

APHIS appreciates the comment and wants to reassure the regulated community that sampling will only be done when absolutely necessary. APHIS accepts that regulated material is proprietary property of the regulated entity and will ensure to take only quantities of samples required for diagnostic evaluation. The language in § 340.5(g)(3) is in line with APHIS' authority under the PPA to conduct inspections. When sampling is done, APHIS follows strict chain of custody protocols. APHIS will protect all proprietary and CBI associated with sampling, and APHIS will only share and results within USDA and with the regulated entity.

Paragraphs (c) and (d) of proposed § 340.5 contained, respectively, exemptions from permitting requirements for interstate movement for GE *Arabidopsis thaliana* and *Agrobacterium tumefaciens,* subject to certain conditions. Some commenters suggested that we consider additional exemptions. One such commenter requested that in addition to *A. thaliana,* APHIS should exempt specialty crops, in which an allele has been edited to align with a similar, known allele in a close relative. Another commenter pointed out that disarmed versions of *Agrobacterium rhizogenes* have an equally useful and safe record for transformation as do disarmed versions of *A. tumefaciens*. The commenter requested that that the exemption for "disarmed *Agrobacterium tumefaciens*" be broadened to "disarmed Agrobacterium strains" or "disarmed members of the *Rhizobiales*", such as *Ochrobactrum haywardense*. Using the same reasons and arguments, the commenter stated that APHIS should consider exempting *Nicotiana benthamiana.* It was also suggested that since disarmed viruses are commonly used in plant molecular biology studies, any pathogen with the pathogenicity demonstrably removed could be

exempted. Some commenters favored even broader exemptions, stating that most types of transgenic plants should also be exempted when shipments are small or in a form in which persistence in the environment is very unlikely. The lack of such exemptions, according to these commenters, impedes collaborative research and breeding substantially.

We agree with these comments in part. Historically, *A. thaliana* and *A. tumefaciens* have been exempted from permitting requirements for interstate movement because interstate movement of the organisms has not resulted in the dissemination of plant pests within the United States. *A. thaliana* has been a research model plant species, and the research community is very familiar with the biological and ecological characteristics. We have had extensive experience assessing the plant pest risks associated with the interstate movement of both organisms. In both cases, the plant pest risks are very low, and safeguards exist that can adequately mitigate those risks. APHIS agrees that other disarmed *Agrobacterium* species can be exempted from the requirement of permits for interstate movement and has revised 340.5(d) accordingly. While some strains of disarmed *Agrobacterium* species may cause mild plant disease symptoms in some cases, given their specific usage in transforming plants, their lack of persistence in the newly transformed plants, and existing practices for shipping *Agrobacterium* strains, there is very low plant pest risk. We do not have sufficient experience with the order *Rhizobiales* to further broaden this exemption. Other GE organisms, such as specialty crops, have not been exempted before, and APHIS does not have extensive experience assessing their plant pest risks. Therefore, APHIS does not think it is appropriate to exempt other GE plants in the same way as *A. thaliana* and *A. tumefaciens*.

As noted earlier in the discussion of the definition of *plant pest*, we are adding to this final rule an exemption from the requirement for permits for import and interstate movement for GE *Drosophila melanogaster,* other than those strains that have been engineered to propagate through a population by biasing the inheritance rate (e.g., gene drives). This exemption is contained in a new paragraph (e) of § 340.5. We have also revised the exemption text for *Arabidopsis thaliana* and *Agrobacterium* strains in § 340.5(c) and (d), respectively, to conform with the revised definition of *genetic engineering*, which is not limited to the insertion of "cloned" genetic material into an organism. Numerous commenters expressed concerns about our proposed permit conditions. Those issues are discussed individually in the paragraphs that follow.

One commenter viewed the permit conditions in general as excessively strict. The commenter stated that the conditions strive toward zero risk, as opposed to the Coordinated Framework criterion of unreasonable risk. It is important to maintain measures commensurate to risk, according to the commenter.

We do not agree with this comment. Our permit conditions are set to ensure containment and confinement of the organism under permit. They are designed to be commensurate with the risk posed by the GE organism.

Some commenters requested that we clarify the distinction between standard permit conditions that apply to all GE organisms and those that apply only to GE plants or to GE microorganisms or insects.

We believe that the standard permit requirements, as listed in § 340.5(h)(1) through (h)(10) of this final rule, make this distinction clear. As written, all the standard conditions listed in § 340.5(h) of this final rule, except for paragraph (h)(6)(ii), which pertains specifically to GE

plant volunteer monitoring, are applicable to all GE organisms. APHIS makes it clear in (h)(6)(ii) that the condition only applies to GE plants by stating that "When the environmental release is of a plant, reports of volunteer monitoring activities and findings must be submitted …" Therefore, we are not making any changes in response to these comments.

One commenter recommended that we adopt a hybrid permit system under which performance standards are primarily used as the enforcement mechanism. According to the commenter, specific permit conditions should be added only when scientifically justified.

We will not be making any changes to the final rule as a result of this comment. Some of the standard permit conditions in § 340.5(h) are, in fact, performance standards. For example, paragraph (h)(1) states that, "The organism under permit must be maintained and disposed of in a manner so as to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment." Under paragraph (h)(6), records related to permit activity by the responsible person must "be of sufficient accuracy, quality, and completeness to demonstrate compliance with all permit conditions and requirements under this part."

As noted in the preamble to the June 2019 proposed rule, however, Office of Inspector General (OIG) audits conducted in 2008 and 2015 recommended, among other things, that APHIS reduce its reliance on performance-based standards generally in regard to the regulations in part 340. While performance standards offer the advantages of administrative streamlining for APHIS and flexibility for regulated parties, there are also significant disadvantages to a performance-standard-based regulatory approach. The absence of specific measures that constitute compliance with the regulations in performance-based standards introduces an element of uncertainty into the process of determining whether a regulated party is in compliance with the regulations. Enforcing the regulations, and thereby protecting U.S. agriculture from plant

pest risks, would thus be made more difficult than it is when compliance measures are clearly enumerated in specific permit conditions, as they always have been under the regulations in part 340 and will continue to be as a result of this rulemaking. Because permit conditions specify which actions need to be taken by the responsible person to be in compliance with the regulations and do not rely as much on subjective determinations by both the responsible person and APHIS personnel as do performance standards, the permitting system provides more risk-appropriate oversight, better regulatory enforcement, and transparency.

A commenter questioned the necessity of the requirement in § 340.5(h)(6) for the submission of a report of no environmental release for all authorized locations where an environmental release of a GE organism did not occur. It was stated that this provision is outside the bounds of the policy laid down in the Coordinated Framework and represents regulatory overreach that cannot be defended and should be set aside. The commenter saw no risk mitigation value in this requirement.

APHIS appreciates the commenter's concern but disagrees with the commenter's arguments. An authorization often covers many sites, and planting may never occur at some sites. Similar to the need for a post-planting report (PPR) to indicate which sites are planted and when, APHIS needs to know which sites were not planted to provide efficient oversight. APHIS thinks that the submission of a report of no release can help the agency track the status of all authorized test field locations in order to account for and sufficiently monitor all such locations, thereby preventing the accidental release of GE organisms into the environment. Additionally, this requirement addresses recommendations issued by USDA's OIG following audits performed in 2015.

One commenter stated that developers may operate under multiple permits for multiple plant-trait-MOA combinations at one time. The plant lines within these multiple permits are planted within proximity to one another to facilitate comparative science and to utilize resources in the most efficient way possible. If APHIS were to issue each permit with different conditions, where the developer may only learn of conditions weeks before planting, these materials may have to be physically separated from each other or research abandoned, inhibiting innovation and increasing the cost to develop new products.

APHIS does not consider this to be likely. The permit conditions for non-PMPI plants are based on the reproductive ecology of the species and the receiving environment. APHIS anticipates that they will be consistent across multiple permits for the same species. The timeframes for the issuance of permits that have been added to the regulations will enable developers to adequately plan to meet the specified permit conditions.

One commenter stated that APHIS should specify in the regulations timeframes for the submission by the responsible person of reports of activities under permit that are required under § 340.5(h)(6).

We do not agree with this comment. The types of reports to be submitted and the timing of their submission will vary by species and, therefore, will be included in each permit in the supplemental permit conditions rather than in the regulations.

One commenter recommended that we allow for changes in the designation of a responsible person via a notification process.

We do not agree with this comment. In § 340.3, we define *responsible person* as the person responsible for maintaining control over a GE organism under permit during its movement and ensuring compliance with all conditions contained in any applicable permit as

well as other requirements in this part. In § 340.5(h)(10), we state that the responsible person for a permit remains the responsible person for the permit unless a transfer of responsibility is approved by APHIS. The requirement for APHIS approval is necessary to ensure that, in the event a transfer becomes necessary, the new responsible person is aware, prepared, and equipped to work with APHIS. That provision does not apply however, to an agent, a term defined in the June 2019 proposed rule as someone designated by the responsible person to act on behalf of the permittee to maintain control over an organism under permit during its movement and ensure compliance with permit conditions. A change in agent may therefore be effected through a notification.

One commenter requested that we not require GPS coordinates in permit-related records, a requirement that is effectively a permit condition, though actually contained in § 340.6, the section covering recordkeeping. The commenter stated that information on actual acreage shortly after planting would suffice.

APHIS disagrees with this comment. GPS coordinates allow APHIS to fully utilize GIS capabilities to implement the procedural provisions of NEPA and to oversee what will be released within the defined authorized area. For example, APHIS needs GPS coordinates information prior to permit issuance to know if a proposed release site happens to be on Federal land or critical habitat.

Paragraph (i) of § 340.5 addresses permit denials and withdrawals. One commenter stated that APHIS must make it clear that the justifications for denial are valid only when the release would likely result in an unreasonable risk to U.S. agriculture. The commenter further suggested that APHIS should include assurances that permits will be presumptively issued unless the Agency can present a plausible argument that to failure to comply with the permitting

conditions would result in such an unreasonable risk. Another commenter suggested that the rule be clarified to indicate that a permit application may be withdrawn by the applicant as well as the Administrator.

We will not be making any changes to the final rule as a result of these comments. Under § 340.5(i)(1), the Administrator will deny a permit application if he or she concludes that the proposed actions under permit may not prevent the unauthorized release, spread, dispersal, and/or persistence in the environment of the GE organism; if the responsible person or agent has failed to comply at any time with any provision of these regulations, a previously issued permit; or if the responsible person or agent has failed to comply with any other regulations issued pursuant to the PPA. Permits will also be denied if the responsible person or agent does not agree in writing to comply with permit conditions or to allow inspection by APHIS. These conditions are necessary to protect U.S. agriculture. Regarding withdrawal, the existing regulations do not specify that permit application may be withdrawn by the applicant. Nonetheless, applicants can request withdrawal of permit applications prior to the issuance of the permit. This will continue to be the case when the revised regulations become effective.

One commenter stated that developers may operate by covering multiple plant-trait-MOA combinations under a single permit. According to the commenter, permits may be requested by location, with many experiments, containing multiple plant-trait-MOA combinations, planted in the same location. If a permit is terminated due to a completed RSR, a termination should not apply to the entire permit, but only for the individual plant-trait-MOA which was reviewed.

In such cases, the permit would not be terminated, and that specific plant-trait-MOA would no longer be regulated under that permit. APHIS would continue to provide oversight for plant-trait-MOAs that are still under permit.

One commenter requested clarification on permit amendment provisions, particularly as they applied to APHIS-initiated amendments in § 340.5(k)(2). The commenter expressed a concern that APHIS may arbitrarily initiate modifications to an existing permit and stated that the Agency should have no authority to initiate such amendments without scientific evidence.

APHIS will not initiate a permit amendment process without sufficient scientific justification. Under § 340.5(k)(2), APHIS will initiate a permit amendment process upon determining that such an amendment is needed to address the plant pest risk posed by the GE organism or the activities allowed under the permit. In such cases, APHIS will provide notice to the responsible person of the amendment(s) and the reasons for it.

Another commenter questioned whether we should include provisions for amending permits in the regulations at all. It was stated that we were reducing our flexibility by including such provisions.

Contrary to the commenter's assertion, we believe that the provisions for permit amendments allow for greater regulatory flexibility by enabling a rapid response to changing circumstances. We have included these provisions to provide an opportunity for a responsible person to request an amendment to permit conditions when circumstance have changed, as opposed to our having to withdraw the permit, which would necessitate that the responsible person then reapply. Under the permit amendment provisions, APHIS would also have the flexibility to amend a permit rather than revoking it if needed to address new or previously unknown plant pest risks presented by the organism.

Another commenter recommended that APHIS specify a timeframe for review of permit amendments requested by a responsible person. The commenter stated that furthermore, APHIS should notify the requester if the amendment request is deemed to be within or outside the scope of the existing permit.

The timeframe for the review for the permit amendment will be the same as for new permit applications and depends on the complexity of the requested change. APHIS has and will continue to let requestors know if an amendment is outside the scope of an existing permit.

Paragraph (l) of § 340.5 contains requirements for shipping under permit. Paragraph (l)(1) contains a performance standard, stating that all shipments of organisms under permit must be secure shipments. Paragraphs (l)(2) and (l)(3) contain, respectively, documentation and labeling requirements, and paragraph (l)(4) contains provisions related to treatment and disposal of shipping containers and packing materials.

One commenter stated that if APHIS' intent at paragraph (l)(1) is to allow developers to make determinations regarding the types of containers used during transport so long as they fit the above stipulations, that represents and an improvement. If this change, however, is meant to be more restrictive, especially with the removal of a variance option, then the responsible person or agent should be able to make changes to shipping container options, if needed.

Paragraph (l)(1) is performance-based. It does not prescribe specific container requirements. The change to the regulations is meant to make the performance standard more explicit while at the same time making the requirements less prescriptive. Based on the definition of *secure shipment* ("Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other

conditions incident to ordinary handling in transportation"), APHIS does not anticipate that shipping variances will be needed.

One commenter requested that we revise the language in § 340.5(l)(4) to take into account reusable shipping containers. The commenter recommended that we replace the word "treated" with "cleaned to remove the organism before reuse."

In response to this comment, we are revising the paragraph to read as follows: "Following the completion of the shipment, all packaging material, shipping containers, and any other material accompanying the organism will be devitalized consistent with supplemental permit conditions, or disposed of to prevent unauthorized release."

Other issues raised by the commenters in relation to permits included concerns about the rigor and integrity of the process, safety of environmental releases under permit, field testing, implementation of the permitting requirements, and the formatting of permits.

One commenter, noting that the definition of *movement* in § 340.3 includes release into the environment, stated that there can be no assurances beforehand of a safe outcome of such a release. The commenter stated that all GE organisms that are to be released into the environment should be subject to strict testing requirements.

APHIS understands the commenter's concerns about safely releasing GE organisms into the environment. For reasons discussed earlier in this document, it is our view that categories of GE organisms that fall under the exempted categories in § 340.1(b) and (c), as well as GE plants that have been subject to an RSR in accordance with § 340.4 and for which APHIS has not identified a plausible pathway by which the GE plant or its sexually compatible relatives could pose an increased plant pest risk relative to the comparator(s), can be safely released into the environment without the need for a permit. The movement, including release into the

environment, of all other GE organisms will only be allowed under permit and subject to strict standard and, if appropriate, supplementary permitting conditions that will effectively mitigate any risks that may be associated with such movement or release.

A commenter stated that granting developers the option to move GE plants under permit in lieu of a RSR raises concerns regarding the integrity and robustness of the regulatory process.

Providing a developer the option to move a GE plant under permit rather than requesting an RSR affords that developer the benefit of maximum flexibility in the research and development of novel GE plants. The provision does not, however, provide the developer a means of evading regulatory scrutiny of new GE plants, as the commenter appears to believe. An RSR results in a determination, based on our evaluation of plant pest risk, that a GE plant either is not subject to the regulations and can be moved with no further restriction under part 340 or is subject to the regulations and may only be moved under permit. Whether a product requires movement under permit as a result of an RSR or because the developer has chosen the permitting option in lieu of the RSR, the GE plant will still be subject to a rigorous screening process. The developer will have to submit a permit application, along with all supporting information required under the regulations. APHIS will carefully review the application and, if warranted, approve it. Prior to issuance, the developer/responsible person will be required to agree in writing that he or she understands and will comply with all the standard and supplementary conditions listed on the permit. Compliance is monitored after a permit has been issued. Our permitting process is a longstanding and rigorous one that ensures that GE plants are moved only under conditions that provide safeguards against the risk of dissemination of plant pests.

One commenter recommended that the implementation of the new permitting provisions and elimination of notifications should be phased in so as to not disrupt seasonal field activities. Other commenters stated that given the magnitude of the changes in regulatory requirements that we proposed, we should phase in implementation so as to allow regulated parties to adjust their operations to comply with the new requirements. Some commenters recommended that we develop timelines for compliance with each component of the proposed regulation. The most common suggested timeframes were 18 months and 2 years. Commenters also requested that we provide guidance on the new regulatory framework to aid them in making the transition.

APHIS understands the commenters' concern and supports a phased approach to implementation. This final rule identifies an effective date for the rule's provisions along with an implementation date for each provision. The exemptions identified in § 340.1, and the confirmation process will become effective and will be implemented 60 days after the publication date of this rule.

The remaining provisions in this rule also become effective 60 days after the publication of the rule; however, APHIS will implement these remaining provisions beginning October 1, 2020. All currently issued notifications and permits will remain valid until the expiration dates specified on such authorizations. APHIS will continue to accept notifications, applications for permits, and petitions seeking nonregulated status in accordance with the current regulations found in part 340, until September 30, 2020. Beginning October 1, 2020, all applications for permits and regulatory status review must be submitted in accordance with the regulations identified in this final rule. This phased implementation mitigates potential disruption to seasonal field activities and will provide developers with the opportunity to review and adjust to the provisions in this final rule.

Commenters stated that APHIS must maintain oversight of field trials, which should only be allowed under permits that mandate stringent gene containment protocols with a management goal of full containment. Safeguards and monitoring must be required for the organism during field trials. Monitoring should include tracking changes associated with ecosystem harm such as degradation of water quality, air pollution, climate impacts, or loss of biological resources. It was also stated that APHIS should publish the results of the agency supervised field trials where they will be publicly accessible. Requirements should include buffer zones for GE crop fields that adjoin organic and non-GE crop fields to reduce GE trait and chemical drift.

APHIS has and will continue to establish isolation requirements for crops grown under permit based on the reproductive ecology of the plant species to prevent gene flow to plants not under the permit.

A commenter stated that APHIS should further clarify the length of time after a permit expires that access to materials and premises must be allowed. As written, such access could be misinterpreted to be in perpetuity, which is unnecessary.

We would require the responsible person to allow access to where the organisms regulated under part 340 are located, including field test sites after trials are harvested or terminated, throughout the volunteer monitoring period, which may continue after permit expiration. Access to premises where regulated organisms are maintained must be allowed even if the permit has expired, unless the product has been devitalized or APHIS has conducted an RSR and determined it to be not subject to this part.

Two other recommendations by commenters were that we develop a database listing the requirements that will be on a particular permit and that we provide for pre-approvals of containment facilities for high-risk organisms, with permits tiered to the approved facility number.

We thank the commenters for these suggestions. APHIS may explore these ideas in the future.

Finally, one commenter stated that each permit should contain a chapeaux, i.e., introductory text, describing the unreasonable risk to U.S. agriculture that the permit is designed to prevent. The commenter further stated that if no such plausible description can be proffered, then APHIS would have no reason for exercising oversight, of or requiring a permit for, the movement of the GE organism for which APHIS intends to issue the permit.

GE organisms will be required to move under permit because, in the case of GE plants, APHIS has conducted an RSR and found a likely or indeterminate plant pest risk, because the developer has opted to go directly to permit rather than requesting an RSR for a GE plant, or because the GE plant or non-plant organism fits under one of the regulated categories in § 340.2. We do not see the need for a chapeaux, as the commenter recommends.

Record Retention, Compliance, and Enforcement

Numerous commenters identified concerns about the record retention requirements described in proposed § 340.6. Issues discussed included overall clarity and scope, timeframes, and reporting requirements.

Some commenters suggested that we needed to clarify our recordkeeping and reporting requirements by adding more specific detail about what information APHIS will require and when.

The reporting and recordkeeping requirements in § 340.6 of the June 2019 proposed rule did provide specific details regarding the types of records that need to be kept and the timeframes for retention, in paragraphs (a) and (b), respectively. At the same time, the requirements we proposed align with our historical approach, which has provided flexibility based on variations in operations performed by different entities and different subparts of a single entity. As reflected in § 340.6(a)(1), which refers the reader back to the permit-related reporting and recordkeeping requirements in § 340.5, many of the recordkeeping and reporting requirements of this rulemaking will depend on the nature of the GE organism and the intended activity and will be included in the permit conditions.

It was suggested that some of the proposed information requirements were duplicative. One commenter stated that APHIS requires information about the location of a field release site to be included in the permit application and then requests the same information again after planting, resulting in duplicate or nearly duplicate records requests. The commenter stated that APHIS also requests the identity of the material being planted (the construct ID) on the application and then requests the same information again on the planting report. According to the commenter, during inspections this information is often requested a third time. The commenter stated that this duplication could be eliminated with no detrimental effects on compliance by having applicants provide it on the permit application and then having APHIS verify it during inspection.

These requirements are not duplicative. Information submitted in a permit application is used for specific release site analysis. Post-planting reports provide the Agency with critical information related to the activity that has been conducted under an APHIS-issued authorization. The information submitted post-planting facilitates effective compliance oversight. Planting

does not occur for every genetic construct and location that is approved in an authorization. APHIS needs documentation (post plant report) of which constructs are planted at each specific field release site in order to perform effective compliance oversight. Additionally, this requirement addresses recommendations issued by USDA's OIG following audits performed in 2015.

A commenter stated that the requirement in § 340.6(a)(2) that all records of locations where organisms under permit are stored should be eliminated. The commenter noted that while APHIS regulates interstate movement, the proposed definition of *move* does not include "store."

We do not agree with this comment. Under § 340.5)(b)(2)(i), all permit applications must include, among other things, information on the origin and destination of a GE organism moved under permit, including information on addresses of all intermediate and final destinations. Additionally, § 340.5(b) states that within the permit application, locations and destination(s) of regulated organisms shall be included. A storage facility is considered by APHIS to be a destination (premises). APHIS needs to know where the regulated GE organism is maintained in order to perform effective compliance oversight.

Commenters expressed concerns about the proposed timeframes for record maintenance. Some thought they were too short to allow the Agency to monitor compliance and respond to incidents effectively, while others viewed them as excessively long and burdensome.

One commenter raised concerns about the Agency's ability to respond to incidents if the Agency only retained records associated with regulatory activities for 2 years.

The commenter may have misunderstood the recordkeeping requirement in § 340.6(b). The requirement that all records indicating that an organism that was imported or moved interstate under permit reached its intended destination be retained for 2 years applies to the

responsible person(s) rather than the Agency. APHIS did not propose any changes to the duration or type of records that the Agency will retain. The proposed 2-year retention requirement did represent an increase from the one in the existing regulations, which was 1 year. APHIS believes this 2-year record retention requirement provides sufficient time to ensure that regulated material has safely and securely reached the intended destination.

One commenter urged us to ameliorate the burden of retaining records of permitted activities for 5 years by offering small entities an option to deposit such records electronically with APHIS for retention.

Certain records are not required to be submitted to APHIS but are to be kept by permitted entities regardless of size in order to demonstrate compliance with permit conditions. Large and small entities alike have the option to retain such records electronically or as hard copies or both, but they must retain them in some form. Records are often reviewed during or after a trial as part of an on-site inspection, or compliance audit, to verify that all conditions have been followed and the fate of the regulated material (devitalized/disposed of, stored, shipped, etc.). APHIS needs to know where regulated material is maintained in order to perform effective compliance oversight. Further, this requirement addresses recommendations issued by USDA's OIG following audits performed in 2015.

Finally, one commenter recommended that APHIS utilize the APHIS-initiated amendment procedure for site-specific enforcement in instances of noncompliance and amend § 340.6(c)(i) to explicitly allow the Administrator to deny an application or withdraw a permit "in whole or part." The commenter contended that this would provide the Agency the flexibility to apply site specific, measured enforcement.

APHIS agrees with the intent of the comment but disagrees that a regulatory text change is necessary because the permit-amendment provisions in § 340.5(j)(2) already allow us sufficient flexibility to respond to compliance issues in the manner recommended by the commenter.

Confidential Business Information

Commenters took divergent views on the issue of the proposed CBI exemptions. Some thought the exemptions, as explained in the preamble to the proposed rule, did not provide enough protection for submitters, while others thought they were too broad.

Several commenters stated that CBI protections should extend to information pertaining to MOA and other information required to be submitted for an RSR or needed by APHIS to confirm a determination by a developer that its product is exempt from these regulations. Some commenters also suggested that submitters may forgo seeking confirmation or an RSR and may opt to go under permits if the MOA will be made public after a product has come through the confirmation or RSR process, because they want to protect that information.

As noted in the preamble to the proposed rule, APHIS intends to release a general description of the plant, the trait, and the MOA of GE plants that go through an RSR without revealing CBI. APHIS would similarly release a general description of the plant, trait, and, as applicable, the MOA associated with confirmation requests without revealing CBI. The Agency wants to clarify that we are not requiring submitters to waive their applicable CBI claims. Further, as we noted in the preamble, certain technical information, such as data that could be used to re-create an organism and that was not otherwise made publicly available by the submitters, may be eligible for CBI designation. To the extent that CBI claims exist, the Agency will review them, consistent with applicable laws and statutory authorities, on a case-by-case

basis. Submitters will be given the opportunity to review the general description prior to public disclosure. Regardless of CBI determination, developers will have the flexibility to select the regulatory options, whether RSR or permit, they deem best for their business needs.

Other commenters expressed concern that extensive granting of CBI designations could impede the ability of developers to determine whether their products are eligible for exemption, and could impede peer-reviewable risk assessment. These commenters favored posting confirmation requests and responses and RSR determinations online. It was suggested that if such data are not available, developers will lack the necessary information to make reliable determinations for their GE plants and may choose permitting instead. As a result, the regulatory relief that is one of the objectives of this rulemaking would be attenuated.

APHIS will post confirmation requests and responses, as well as determinations of nonregulated status pursuant to the outcomes of initial RSRs, on the APHIS website, with CBI redacted. When additional review is requested, as discussed earlier in this document, the analysis, outcome, and supporting documents will be published in the *Federal Register* and on the website, also with CBI redacted. We recognize that, in some cases, information necessary for researchers and developers to make determinations pursuant to 340.1(c) may not be made public due to CBI claims.

Commenters also expressed the view that mandatory field trial data should not be eligible for CBI exemption.

Under this rulemaking, there is no requirement that developers submit field-trial data to APHIS, though they may do so if they choose to support an RSR or confirmation letter request. As noted above, APHIS would only allow CBI exemptions that are consistent with applicable case law and statutory authorities.

A commenter requested that we clarify how the process for submitting CBI exemption requests and justifications for exemptions differs from that in the current regulations.

The process for submitting and justifying CBI claims will not change under this rulemaking. Persons submitting any document to APHIS in accordance with the regulations must identify those portions of the document deemed to be CBI. Each page containing such information must be marked "CBI Copy." A second copy of the document must be submitted with all such CBI deleted, and each page where the CBI was deleted must be marked "CBI Deleted." In addition, any person submitting a CBI exemption request must justify the request by demonstrating how each piece of information to which the request applies is a trade secret or is commercial or financial information and is thereby privileged or confidential.

Economic Analysis

Some comments directly addressed the economic analysis that accompanied the June 2019 proposed rule. It was claimed that the analysis was light on data characterizing the potential economic and social impacts of the proposal. It was also stated that we did not offer sufficient analysis of the challenges of assuring other countries that imports of GE products from the United States are safe and meet the importers' requirements.

In the analysis accompanying the June 2019 proposed rule, we did request comments from the public on the potential economic impacts of the rule on affected entities. Most of the commenters who addressed potential economic impacts did so as part of a broader discussion of other issues, such as the potential economic effects of commingling, rather than addressing the economic analysis directly. Commenters did not supply actual data that would have aided us in characterizing potential social and economic impacts of the proposed rule. We do discuss potential international trade issues at some length later in this document.

Regulation of Plants that Produce Plant-Made Industrials and Pharmaceuticals (PMPIs)

As we explained in the preamble to the 2019 proposed rule, the likelihood exists that most, if not all, GE PMPI-producing plants that are currently under APHIS permits could be determined to be not regulated if an RSR found them to be unlikely to pose a plant pest risk. Thus, such plants could be grown outdoors without the need for APHIS permits and without APHIS oversight.

We received many comments on this issue. Some commenters expressed concern that the proposed change to our regulatory approach to PMPI's would weaken or eliminate APHIS' oversight of them. Others favored less regulatory oversight of PMPIs than that which was provided for in the existing regulations or would be if we were to regulate PMPIs under 7 CFR part 360. Other commenters requested that we provide greater clarification of our regulatory approach to PMPIs under this rulemaking and emphasized the need for cooperation among regulatory agencies. These issues are discussed in greater detail below.

Some commenters stated that as a result of this rulemaking, APHIS would abdicate its oversight role, leaving the planting of PMPIs essentially unregulated, since FDA has no jurisdiction in that area. As a result, our agricultural food systems could be made vulnerable to introduction of experimental GE crops, and environmental quality and human health could be negatively affected simply based on the end use of those crops for pharmaceuticals or industrial purposes. One commenter expressed concern that PMPI developers would be able to determine for themselves whether their products are eligible for exemption.

All of these commenters urged us, at a minimum, to revise the final rule so as to maintain our regulatory oversight of PMPIs. Some commenters favored still more stringent requirements.

It was argued that APHIS should invoke its noxious weed authority to prohibit the outdoor planting of PMPIs altogether.

As noted above, like any other GE plant submitted for an RSR, a PMPI would be subject to the regulations if we find that there is a plausible pathway to increased plant pest risk than its comparator and we cannot determine that the GE plant is unlikely to pose such a risk. This approach reflects our current thinking regarding the implementation of our existing authority under 7 CFR 340 in relation to PMPIs. APHIS will continue to explore additional options for regulatory oversight of PMPIs, under the authority provided in the PPA, as appropriate.

Some commenters argued in favor of more restrictive oversight of PMPIs than was provided for either in the proposed rule or the existing regulations. It was stated that allowing PMPIs to be grown outdoors without APHIS oversight does not comport with the OIG's recommendations on regulating PMPIs to prevent inadvertent release.

We do not agree with these comments. In 2003 APHIS issued stricter requirements for PMPI field trials than those in effect at the time. These requirements included adding location coordinates or identification to the permit conditions in low-production geographies, requiring dedicated equipment, and providing for frequent inspections of each trial site. APHIS believes that these and the other measures that we have imposed are adequate to mitigate the possibility of gene flow from PMPIs to neighboring food crops. The changes to the regulations resulting from this rulemaking will not affect these requirements.

Other commenters took the view that APHIS' regulatory oversight of PMPIs was, if anything, already excessive and would remain or become still more so under the proposed rule. One commenter stated that developers should be given the option to be regulated by the agency most relevant to their GE products. The commenter offered as an example a developer of PMPIs

choosing the FDA to oversee its products. Other commenters stressed the need for APHIS and FDA to have a memorandum of understanding (MOU) for the regulation of PMPIs.

APHIS agrees that it makes sense that FDA would regulate PMPIs because the primary potential harm they pose is a matter of human health and not plant pest risk. APHIS has explored with FDA the possibility that APHIS would continue to regulate PMPIs under FDA authority using an Economy Act agreement. Under such an agreement, APHIS would continue to administer the trials, but FDA would reimburse the Agency, since the authority falls under FDA's jurisdiction. During our discussions, however, APHIS learned that FDA's authority did not begin until an Investigational New Drug application was submitted. Typically, these applications are not submitted until clinical trials are about to begin, which is substantially later than when PMPI field trials would begin. From our discussions, we could not find a suitable approach where FDA regulated these field trials, and thus is it not clear how an MOU between the two agencies would facilitate such regulation.

One commenter recommended that we list categories of the types of PMPI-producing plants that could generate undesirable food adulteration, should they find their way into the food supply, and regulate only those.

Another commenter stated that we needed to clarify and possibly refine our overall regulatory approach to PMPIs. The commenter expressed a concern that a lack of clarity may result in unnecessary costs and time delays in bringing new products to market, thereby disproportionately impacting smaller developers and limiting the availability of new opportunities for farmers. As an example of a possible refinement to our regulatory approach, the same commenter suggested that in regulating PMPIs, APHIS should consider the likelihood

that PMPIs will be produced in niche crops, which can be readily segregated from commodity crops, thus reducing the potential for them entering the food chain.

As noted above, the primary oversight authority in matters concerning food safety rests with FDA rather than APHIS. When establishing requirements for PMPI field trials in order to mitigate the possibility of gene flow to neighboring food crops, APHIS takes into consideration the specific crop in which the PMPI is produced.

Regulation of Plant-Incorporated Protectants (PIPs)

As noted in the preamble to the June 2019 proposed rule, certain plants are genetically engineered to produce PIPs, meaning that they produce pesticides. PIPs fall under the regulatory oversight of EPA; however, historically, only APHIS has exercised regulatory oversight of PIP plantings on 10 acres or less of land.

Under the provisions of the June 2019 proposed rule, there is a likelihood that many GE PIP-producing plants that are currently regulated under APHIS permits or notifications could be determined not to be covered by the regulations after RSRs because they are unlikely to pose increased plant pest risks than their comparators. Such plants could therefore be grown outdoors without the need for an APHIS permit and without undergoing APHIS oversight. Thus, Federal oversight of small-scale (10 acres or less) outdoor plantings of some PIPs would shift from APHIS to EPA.

Some commenters stated that APHIS should continue its oversight of PIPs in coordination with EPA to ensure that PIPs are regulated at all scales. It was also stated that regulation of PIPs should be left entirely to EPA.

APHIS will continue to conduct oversight of PIPs at all scales until it determines that a PIP does not pose a plant pest risk. If APHIS determines the PIP does not pose a plant pest risk,

the PIP would be designated nonregulated status and the decision will be up to EPA as to whether it wishes to provide oversight of field trials under 10 acres. APHIS has avenues for cooperation with EPA, such as an agreement to provide oversight assistance to EPA under the Economy Act, should EPA decide that oversight of small PIP field trials is appropriate.

Other commenters expressed concern that small releases of PIPs that are not currently subject to APHIS regulations could be regulated under the proposed rule.

The June 2019 proposed rule did not expand the scope of APHIS' regulatory oversight of PIPs.

Finally, one commenter stated that regulating PIPs more strictly than regulating chemicals is not scientifically justifiable.

This comment is beyond the scope of the current rulemaking.

International Trade Implications

A number of commenters expressed the concern that the regulatory approach that underpins this rulemaking is out of step with that of key international markets and governments. It was suggested that the rule could result in greater asymmetry in regulatory approach between APHIS and U.S. trading partners, thereby endangering U.S. export markets, and that obtaining international acceptance of our new regulatory approach should be a precondition for finalization. A commenter further stated that we need to balance our regulation of GE organisms with the need for industry to comply with international markets that are sensitive to "." the unintended presence of GE organisms in non-GE products.

The fundamental APHIS protection goal under our regulations in 7 CFR part 340 is to protect agriculture against increased plant pest risk resulting from a GE organism. This regulatory approach has always been different from that of other national systems, which do not necessarily focus on plant pest risk and instead are technique-based. Nevertheless, our trading

partners have always judged our approach to be acceptable, as it is transparent, science- and risk-based. Trading partners that have understood and accepted our regulatory system historically will not find our updated approach to meeting the same objectives confusing. Thus, we do not see this revised system as being less compatible with those of our trading partners than in the past. As we have in the past, we will continue to provide technical expertise, information, and explanation regarding our regulatory system and determinations of regulatory status.

It was further stated by commenters that a possible consequence of trading partners not accepting our new regulatory approach could be the undermining of the progress being made in the Global Low-Level Presence Initiative (GLI), in which countries (including the United States) are striving to achieve a science- and risk-based approach that would allow for a commercially achievable tolerance for the presence of a biotechnology-enhanced trait that has been approved as safe by a country based upon scientific analysis and CODEX-adopted risk assessment principles, but not yet by an importing country. Indeed, the U.S.-Mexico- Canada Agreement expressly commits all three countries to develop a low-level presence policy for imports.

To achieve global acceptance for its new regulatory approach, APHIS needs to maintain its credibility and its leadership role in the field of biotechnology regulation. It was with that goal in mind that we proposed these new regulations, which reflect both the knowledge we have gained over the more than 30 years since we first promulgated our biotechnology regulations and new developments in the field.

While it is gratifying that the APHIS system of regulation is perceived to provide protection against commingling or low level presence of plant products unwanted or unauthorized in foreign (or even domestic) markets, the PPA, under which these regulations are

promulgated, does not authorize APHIS to use the potential for low level presence as a basis for determining regulatory status or monitoring what has been commercialized.

Elaborating on the concerns discussed above, some commenters emphasized the need for APHIS to develop and execute an international engagement strategy with our trading partners that explains the rationale for APHIS' pre-market regulatory approaches.

For 30 years, APHIS has consistently engaged and led in many international contexts to provide knowledge of its regulatory policy, science, and systems to encourage the safe development and trade of the products of agricultural biotechnology. Most recently, APHIS has worked to implement of the Presidential Executive Order *Modernizing the Regulatory Framework for Agricultural Biotechnology Products* (June 11, 2019, E.O. 13874) to "provide leadership in international fora to promote scientific competency, understanding of the U.S. regulatory approach, and regulatory compatibility worldwide for biotechnology products.[7]" For the past several years, APHIS has shared rationales, experience and information on potential regulatory changes with U.S. trading partners, like-minded countries, and other countries in order to garner understanding and support for this updated regulatory approach. APHIS intends to continue such engagement.

Statutory Authority, Jurisdiction, and Interagency Coordination

We received many comments regarding our statutory authority, or lack thereof, to implement our proposed regulations. Some commenters claimed that we did not have such authority, while others expressed the view that we were abdicating the authority we do possess and, in some cases, failing to meet our statutory obligations. Some of these issues have already

[7] National Strategy for Modernizing the Regulatory System for Biotechnology Products. September, 2016

been discussed elsewhere in this document in relation to topics such as allowing developers to determine whether their products are eligible for exemption.

As noted above, we base our determinations of regulatory status on whether a GE plant or its sexually compatible relatives could pose an increased plant pest risk relative to the comparator(s). One commenter asserted that the PPA only gives the Secretary the authority to develop regulations for the movement of plant pests and not the authority to develop regulations for the movement of organisms that pose a plant pest risk.

We do not agree with this comment. In addition to the authority to regulate the movement of plant pests under § 7711 of the PPA, including "[a]ny article similar to or allied with any of the" the specific plant pests listed in § 7702(14), as cited by the commenter, we note that § 7712 of the PPA specifically provides the Secretary with broad authority to protect plants by regulating the movement of, among other items, plants and articles in order to *prevent* the introduction or dissemination of a plant pest within the United States.

As noted many times in this document, for GE organisms that fall under the regulations, permits are required for three activities: Importation, interstate movement, and environmental release. One commenter asserted that regulation of environmental releases done within a State or territory is unconstitutional.

We do not agree with this comment. The impact of an unauthorized environmental release may extend beyond the borders of the State in which the GE organism was released.

In contrast to the comments discussed above, which questioned the reach of our authority to regulate, other comments faulted us for not using our authority to regulate noxious weeds under the PPA. It was stated that by not considering noxious weed potential as a criterion for determining regulatory status of GE organisms, we restrict our authority under the PPA. One

commenter argued that APHIS is statutorily obligated to integrate and apply the noxious weed authority to GE crops.

APHIS recognizes that genetic engineering may be used to introduce a trait that increases the distribution, density, or development of a plant or the weedy impacts of the plant, factors that are considered aspects of a plant's weediness. As such, we would continue the current practice of considering the weediness of the unmodified plant and whether the new trait could in any way change the weediness. We would also consider potential effects on the weediness of other plants with which the engineered plant can interbreed, because it is relevant to the assessment of the plant's plant pest risk. Plants and their sexually compatible relatives could have increased importance as reservoirs for plant pests if they are distributed differently, are more prevalent, or are altered in the timing during which they serve as a host for plant pests due to the introduced trait. As part of the regulatory status review, APHIS would continue to consider whether the trait might change plant pest interactions, establishment, and persistence for both the plant engineered, and any other plants with which it can interbreed. Second, if the plant had the potential to be a truly troublesome and impactful weed, we would need to consider whether the plant with the specific trait being evaluated should be considered for regulation pursuant to our statutory authority and the regulations issued under that authority. The proposed regulation does not change this analysis.

APHIS disagrees that APHIS is statutorily obligated to integrate noxious weed authority into a revised 7 CFR part 340. In the PPA, Congress identified plant pests and noxious weeds as separate concerns, and delegated authority to the Secretary to determine how to best use this authority.

Other commenters expressed the concern that by asserting our statutory authority narrowly and emphasizing deregulation in this rulemaking, we could be creating a regulatory vacuum. It was suggested that States or localities may take advantage of that vacuum and assert their own authorities, possibly intervening to disrupt necessary field trials.

The regulations proposed under this part provide the same functional equivalency as the rules under which APHIS has been operating under for essentially three decades. Under the existing regulations, APHIS communicates with and cooperates with State and local governments as appropriate and as circumstances warrant, including for coordination of enforcement and permitting activities. APHIS does not anticipate that the working relationship with State and local governments will be changed in any way based upon issuance of this rule.

Some commenters addressed issues of interagency and intra-agency coordination in the regulation of GE products. A commenter suggested that we needed to coordinate with EPA to improve the commercial availability of herbicide resistant crops concomitant with the registration of herbicides for use on those crops. The commenter stated that the two agencies' asynchronous timing of the deregulation of an herbicide-resistant crop cultivar and the associated herbicide registration has led to some scenarios where growers are tempted to illegally apply unregistered herbicide formulations. Another commenter stated that duplicative regulations from oversight agencies, including FDA, EPA, and APHIS, should be streamlined into a common regulatory oversight regime depending on the product and its intended use.

With regard to the former commenter, we note that one of the purposes of the Coordinated Framework is to ensure that there is a standard mechanism for communication and, to the extent possible, coordination among FDA, EPA, and APHIS as they perform their respective regulatory functions.

With regard to the latter commenter, while FDA, EPA, and APHIS have distinct regulatory jurisdictions relative to GE organisms, the Agencies are committed to the aims of Executive Order 13874, particularly its exhortation to streamline regulations and guidance documents that fall within each respective Agency's purview.

Finally, one commenter recommended that we provide greater clarity regarding the regulatory jurisdiction of two agencies within APHIS— Biotechnology Research Services (BRS) and Plant Protection and Quarantine (PPQ)—that regulate, among other things, GE and non-GE plants, respectively. The commenter expressed concern that some of the revisions we proposed, in particular those in § 340.2, may create opportunities for duplicative regulation of products under 7 CFR part 340 by BRS and under 7 CFR part 330 by PPQ.

The regulations in 7 CFR part 330 govern the movement of plant pests, biological control organisms, and associated articles, such as soil. Prior to a final rule[10] published in the *Federal Register* on June 25, 2019 (84 FR 29938-29967, Docket No. APHIS-2008-0076), the regulations in 7 CFR part 330 had specifically exempted from regulation under that part any plant pests that had been genetically engineered, as that term was defined in 7 CFR part 340.1. In the June 25, 2019 final rule, that specific exemption was removed from 7 CFR part 330. In its place, a requirement, currently found in paragraph (a) § 330.200, was added. This new requirement provided that plant pests, biological control organisms, and associated articles that are not authorized importation, interstate movement, or environmental release in accordance with 7 CFR part 330 or explicitly exempted from regulation under 7 CFR part 330, must be

[10] To view the rule, its supporting documents, or the comments that we received, go to https://www.regulations.gov/docket?D=APHIS-2008-0076.

authorized importation, interstate movement, or environmental release under other regulations in 7 CFR in order for that movement to be lawful.

The intent of this revision was to signal that there are multiple parts in 7 CFR, not just part 340, that contain requirements regarding the importation, interstate movement, or environmental release of plant pests, biological control organisms, or associated articles. However, we agree with the commenter that one of the unintended effects was that the clear delineation between the requirements for the movement of GE plant pests, which are found in 7 CFR part 340, and the requirements for plant pests that had not been genetically engineered, which are found in 7 CFR part 330, had been lost.

Accordingly, we are revising § 330.202 to indicate that GE plant pests and biological organisms are exempted from regulation under 7 CFR part 330, and are regulated under 7 CFR part 340.

A commenter expressed the concern that this rulemaking does not further the Coordinated Framework established in the 1980s among USDA, FDA, EPA regarding federal biotechnology regulation. The commenter states that the proposed rule amended part of this Coordinated Framework without the full engagement of EPA and FDA in a manner that provides a holistic approach to update the regulatory landscape for certain GE plants. The commenter strongly believes that APHIS should follow the intent of the Coordinated Framework.

APHIS coordinates with our Coordinated Framework partners at the FDA and EPA, and we are committed to continuing this coordination with the implementation and operationalization of this rule. Additionally, as part of the rulemaking process EPA and FDA have had the opportunity to comment on this proposal and to provide meaningful insight that informed this process.

Another commenter stated that language in the section of the proposed rule describing regulation of plants that produce PMPIs suggests that the Coordinated Framework for regulating GE crops in the U.S. is not nearly as "coordinated" as is necessary to ensure the safety of our food supply. A statute should be enacted to create a new Federal agency that would have explicit authority to provide oversight of all GE organisms, GE plants and GE animals and GE microorganisms, for all possible risks including: plant pest and noxious weed risks, environmental risks to beneficial organisms as well as to "neutral" organisms like monarch butterflies, and human health risks like those associated with animal carcinogens and probable human carcinogens like glyphosate.

The comment is outside the scope of the current rulemaking and of APHIS' regulatory authority.

NEPA Implementing Regulations

As noted earlier, under the June 2019 proposed rule, the notification and petition processes were removed from the regulations. Concurrently, we proposed to remove language pertaining to notifications and petitions from the NEPA implementing regulations in 7 CFR part 372. Specifically we proposed to remove language pertaining to notifications from § 372.5(c)(3)(iii) and to petitions from paragraphs (b)(7) and (c)(4) of § 372.5. These changes were proposed to make the NEPA regulations consistent with those of the revised part 340.

Several commenters recommended that the Agency revise its NEPA implementing regulations to ensure that individual actions taken under the proposed rule are appropriately addressed and describe the type of environmental analysis and documentation that will generally be developed. One commenter stated the Agency should revise § 372.5(b) to include the proposed RSR as a type of action that normally requires an environmental assessment but not

necessarily an Environmental Impact Statement. Another recommended that APHIS clarify that certain actions are not expected to have an impact on the environment and therefore qualify for a categorical exclusion from the requirements of NEPA.

APHIS disagrees that 7 CFR part 372 needs to be further revised to more specifically describe the type of environmental analysis that is necessary for individual actions under the final rule. Actions will be accompanied by appropriate environmental analysis based on the degree of environmental impact as described in the final programmatic environmental impact statement (PEIS). In regards to the new proposed RSR, APHIS stated in the final PEIS that RSRs will be accompanied by an appropriate environmental analysis depending on the degree of environmental impact.

APHIS seeks to further clarify the Agency's NEPA obligations under various circumstances. When a modified plant qualifies for one of the exemptions in § 340.1(b) or (c), the plant is not subject to 340 and, therefore, APHIS will not complete a NEPA analysis for it. In the case of RSRs, whether conducted prior to or after a person requests a permit, only some outcomes will require analysis pursuant to NEPA. If, after initial review, APHIS finds a plausible pathway to increased plant pest risk, APHIS will conduct a Plant Pest Risk Assessment (PPRA) to evaluate the factor(s) of concern. In this situation, APHIS will complete a NEPA analysis, as appropriate, for an unconfined environmental release. Finally, when permits are issued for confined environmental release, NEPA will apply as appropriate. Under most circumstances, confined environmental releases are categorically excluded in part 372 from the need to prepare an Environmental Assessment or an Environmental Impact Statement.

List of Taxa

In the preamble to the June 2019 proposed rule, we noted that we were removing the list of taxa containing plant pests from the regulations. Instead APHIS proposed to maintain a list of taxa that contain plant pests on its website. We explained that the list on the website would be more useful and reliable than a static list of taxa, which becomes outdated. We solicited public comment on the proposed change.

Commenters supported this change. One commenter, however, suggested that it would be useful to maintain a version history on the website, so developers can be aware of the latest updates. The commenter also recommended that whenever the website is updated, APHIS should send an email notification to stakeholders. Another commenter requested clarification on how the list would be maintained and modified.

APHIS agrees with the comment. Since taxonomic designations sometimes change and new plant pests are continually being discovered, APHIS will maintain a version history for the list of taxa that contain plant pests and will provide an email notification to stakeholders when the list is changed.

Oversight and Transparency

Some commenters expressed the concern that the regulatory framework set forth in the June 2019 proposed rule would result in an overall weakening of APHIS' regulatory oversight of GE products. Commenters discussed a number of potential consequences of APHIS' diminishing oversight role. As noted earlier in the discussion pertaining to allowing developers to determine whether their products are eligible for exemption, there could be an increased risk of commingling of non-GE crops with GE crops. It was also stated that since GE crops are already associated with greater herbicide and pesticide use than non-GE crops, the rule could

result in the development of more herbicide- and pesticide-resistant pests and weeds, leading to increased environmental and human health risks. Some commenters stated that we needed to strengthen, rather than loosen, our regulatory oversight.

We have addressed many of these issues earlier in this document and the PEIS. Additional discussion is presented below, under the heading "General Opposition to GE Products." As we have noted, however, these issues are mostly outside the scope of the current regulations and of our statutory authority under the PPA.

It was also suggested that the proposed new regulatory framework could lead to a loss of transparency. Growers of non-GE crops, as noted above, could lose access to information about neighboring GE crops. According to some commenters, the public would also lose access to important data. In particular, field-test data would no longer be available to the public because the submission and publication of such data would not always be required under the proposed rule.

One commenter recommended that in addition to providing the information currently set forth in the proposed rule, APHIS should establish on its website a single list of all GE organisms that are being released into the environment. That list should include all plant-trait-MOA combinations, all RSRs, all permitting, and all confirmations of developers' determinations of an exemption. With a complete and accurate list of all GE organisms that have been released into the environment, food industry stakeholders and the public will be able to determine which GE plants have entered the food supply. A transparent and comprehensive list will provide helpful information if any food safety and environmental threats materialize. This information will also be important for international trade because it may prevent unnecessary trade barriers from being constructed based on inaccurate information about which GE plants

may be entering a country without the proper regulatory approval. It will improve consumer confidence about GE plants because consumers will realize that their existence is not being hidden from them. To be as useful and as transparent as possible, the list should include information about the plant, the type of modifications or edits performed, the changed traits, a summary of data about the benefits of the traits, and any testing for safety concerns.

We do not agree with these comments. Under this rule APHIS will continue to make available information related to permits issued under § 340.5. APHIS will also make available information on responses to confirmation requests under § 340.1 and on RSR requests and results under § 340.4. A list of all GE organisms, including those that are not regulated by APHIS, is not a provision of this part, as such a proposal would exceed the scope of the authority under the PPA.

General Opposition to GE Products

A great many commenters opposed the rule because of their concerns about GE products generally. An issue of particular concern, raised by a very large number of commenters, was the possibility of unsafe GE products getting into the food supply without consumers' knowledge. Many of the commenters favored labeling of foods derived from GE products. Commenters expressed the view that genetic engineering techniques are not as safe as traditional breeding techniques and that all GE products should be regulated, with no exemptions allowed. Others stated that we should require long-term testing of GE products prior to allowing commercialization. It was further stated that in light of these considerations, our proposed regulatory approach, with its focus on unfamiliar GE products, does not adequately evaluate GE products for potential long-term risk. Many commenters argued that all GE organisms should be subject to assessments of their long-term effects on the environment and human health and also

evaluated for indirect economic effects. Commenters also claimed that the proposed rule, with its deregulatory emphasis, favored certain economic interests at the expense of public health and safety and the environment.

One commenter further stated that APHIS or a new GE-organism-specific agency should provide oversight of all GE organisms for all possible risks, including any associated with the MOA used for gene insertion, e.g. extra antibiotic-resistance genes, insertional mutations, unintended changes in the inserted genetic material (such as the unintended rearrangements, point mutations, and chimeric RNA derived from donor and recipient DNA sequences found in the commercial product NK603). According to this commenter, APHIS should require developers of GE organisms to utilize the precision of the technology available to identify the imprecise products of genetic engineering and ensure the risks associated with any of them are minimal.

The comments discussed above appear to be based on the premise that that the genetic engineering process itself is inherently risky. As we noted in the preamble to the June 2019 proposed rule, and in this document, available evidence, including reports from the National Academies of Sciences, Engineering, and Medicine cited earlier in this document, does not support this view.

In the reports we cited, issued in 1987 and 1989, respectively, by the NRC[6,7], it was stated that there was no evidence for unique hazards inherent in the use of recombinant DNA

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[6] Introduction of Recombinant DNA-Engineered Organisms Into the Environment: Key Issues. 1987. NRC. Washington, DC. National Academies Press (US).

[7] Field Testing Genetically Modified Organisms: Framework for Decisions. 1989. NRC (US) Washington (DC). National Academies Press (US).

techniques and that with respect to plants, crops modified by molecular and cellular methods should pose risks no different from those modified by classical genetic methods for similar traits. A key conclusion from these reports taken together, is that it is not the process of genetic engineering *per se* that imparts the risk, but the trait or traits that it is used to introduce. A more recent NAS report, issued in 2016, reaffirmed this conclusion.[8]

Several commenters took a position diametrically opposed to the comments discussed above. The commenters stated that there is no scientific rationale for the continued regulation of plant products developed using genetic engineering techniques and legacy methods.

We do not agree with this comment. As discussed above, responsibility for regulating GE and non-GE plants is divided between APHIS BRS and APHIS PPQ. In both cases, plants and plant products are regulated or not regulated based on the risk of introducing or disseminating plant pests that may be posed by their movement or release into the environment. Because some GE and non-GE plants are associated with increased risk, it is necessary for APHIS to regulate them in order to carry out its mission of protecting U.S. agriculture.

Concerns were expressed by the organic farm industry regarding the economic impact the regulatory relief offered to developers in this rulemaking will have on organic farmers, particularly as it relates to the issue of GE crops commingling with organic crops. The commenters stated that APHIS must consider how it will address the needs of USDA-certified organic operations to prevent commingling with GE organisms. Such considerations, it was stated, were not addressed in the proposed rule. The commenters noted that the USDA National Organic Program regulations prohibit the use of genetic engineering in the production of

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[8] NAS. 2016. Genetically Engineered Crops: Experiences and Prospects. Washington, DC: The National Academies Press. doi: 10.17226/23395.

agricultural products marketed as organic in the U.S. Even inadvertent presence of GE organisms can jeopardize the organic status of an otherwise compliant organic product, and lead to loss of markets and significant industry disruption. Organic farms that experienced crop loss from the presence of GE organisms between 2011 and 2014 reported an average loss of $70,000 per farm (2014 USDA Organic Survey).

APHIS has fully considered these factors from an economic perspective and would refer the commenter to the economic analysis documents accompanying this final rule.

One commenter stated that in addition to the threat of economic harm from unintended presence of GE plant material, farmers who unintentionally grow patented GE seeds or who harvest crops that are cross-pollinated with GE traits could face costly lawsuits.

The issue raised by the commenter is outside scope of the plant pest authority delegated to APHIS under the PPA.

It was argued that APHIS should conduct ongoing monitoring and assessment of GE product impacts through both pre-market field trials and following commercialization in order to protect the integrity of conventional and organic seed and crops from prohibited substances and excluded methods, including the methods of genetic engineering. Safeguards and monitoring must be required for the organism post-commercialization. The FDA GRAS (Generally Regarded as Safe) process is not enough for such safeguards. Monitoring should include tracking changes associated with ecosystem harm such as degradation of water quality, air pollution, climate impacts, or loss of biological resources. This process must be rigorous, transparent, and inclusive of APHIS's plant pest and noxious weed authority under the PPA.

APHIS does not agree with these comments. Once APHIS determines that a plant product does not pose a plant pest risk, the Agency has no further authority to regulate and

mandate requirements for the submission of data, unless there are new facts, such as a compliance incident, that warrants such action.

One commenter discussed the need for compensating organic and other growers of non-GE crops who could suffer harm as a result of this rulemaking. It was argued that we need to establish a compensation mechanism for those harmed by commingling, and that liability in cases of commingling caused by GE crops should rest with the developers or patent holders. One commenter also recommended that we establish a fair compensation mechanism for losses caused by herbicides drifting from fields planted with herbicide-resistant GE plants.

We thank the commenters for these recommendations; however, they fall outside the scope of the regulations in part 340, which establish the oversight and regulation of certain GE organisms. Regarding the latter comment, application protocols/practices for pesticides are established and enumerated through EPA's labeling requirements. Once APHIS determines that a plant products does not pose a plant pest risk, the Agency has no further authority to regulate and mandate requirements for the submission of data, unless there are new facts, such as a compliance incident, that warrant such action.

Additional Comments

Commenters offered a number of additional recommendations that are beyond the scope of the current rulemaking. Some commenters recommended that we invest in research to develop lower-cost rapid testing technology. It was further suggested that we commit resources to researching, tracking and analyzing incidences of unintended GE presence and associated economic losses at all levels of the supply chain. One commenter recommended that we coordinate with Agricultural Marketing Services to establish contract protections for organic and identity preservation grain growers to ensure they have fair access to testing data and recourse.

We thank the commenters for these recommendations. As noted above, however, all of these recommended activities would fall outside the scope of the regulations in part 340, which establish the oversight and regulation of certain GE organisms.

One commenter stated that APHIS should consider protection goals that align with making U.S. agriculture more sustainable, more environmentally friendly, and less in need of future "solutions" to genetic engineering-produced noxious weed problems that involve developing additional GE crops engineered to be tolerant of different, more noxious herbicides.

This comment is outside the scope of these regulations. The PPA provides for detection, control, eradication, suppression, prevention or retardation of plant pests or noxious weeds.

Another commenter expressed concern over biodiversity and food security in the context of accelerating climate change. The commenter stated that genetic uniformity leads to disease susceptibility and that biodiversity management systems need to be improved in terms of equity. We need systems that support keeping diverse seeds in use. Genetic engineering, however, has gone hand in hand with large monoculture production.

This comment is outside the scope of these regulations.

Other commenters expressed concerns about corporate concentration and feedback loops of seeds and chemical use, attributed to Corporation Concentration. Particular concern was expressed over the possible consolidation of the seed industry that commenters thought could result from this rulemaking. It was stated that legal and government systems favor the largest companies, and efforts to check the power of the largest seed companies have been overridden or have fizzled out.

APHIS understands and appreciates the concern that the commenters have raised on this topic. The regulations proposed under this part are intended to streamline and offer additional

regulatory relief to developers of all sizes. We anticipate that since smaller-scale business and academics have limited resources and capacity to navigate regulatory systems, this rule will provide especially acute benefits to smaller researchers and businesses. APHIS has outlined and provided detailed descriptions of this dynamic in the economic analysis accompanying this regulation.

Some commenters opposed the elimination of the notification and petition procedures contained in the existing regulations. It was stated that APHIS should not eliminate the petition process without more clearly defining a streamlined, predictable path through which responsible individuals can establish that their innovation no longer needs to be reviewed by APHIS prior to release/commercialization. Commenters opposed eliminating the notification procedure because many developers would then be obligated to go to permitting, resulting in possible disruptions to business practices. Alternatives suggested by these commenters included adding a provisions for streamlined permitting with standardized conditions for low-risk organisms and returning to requiring individuals to provide info on how they intend to meet performance standards.

In many ways, the APHIS evaluations for notifications are very similar to those done for permit applications, but the notification procedure relies on applicants agreeing to meet the performance-based standards described in the regulations rather than submitting an application for APHIS review describing the specific measures they will employ for the activity (as is the case for permits). With permits, but not with notifications, APHIS can accept the proposed measures or add to them, and the result is a set of binding customized permit conditions.

We will not be making any changes in response to these comments. As we noted in the preamble to the June 2019 proposed rule, the notification procedure in the regulation relies upon performance-based standards. Since the specific measures that constitute compliance with the

regulations are not enumerated in the performance standards, it can be difficult for APHIS inspectors to determine if a notification holder is in compliance. This uncertainty can make enforcing the regulations, and thereby protecting U.S. agriculture from plant pest risks, more difficult than it would be if compliance measures were clearly enumerated as they are in specific conditions under a permit. For this reason and to comply with OIG recommendations, we proposed to eliminate the notification procedure. We do not agree with the recommendation to provide streamlined permit conditions for low-risk organisms. The standard permitting conditions in § 340.5(g) are needed to ensure that activities conducted under permit for all GE organisms can be performed with adequate mitigations for plant pest risk. Differences in the level of risk associated with different organisms will be reflected in the supplemental permitting conditions.

The current petition process for GE plants stems from the manner in which *regulated article* is defined. As noted above, the current regulations consider a GE organism to pose a plant pest risk and therefore be a regulated article if the donor organism, recipient organism, vector, or vector agent is a plant pest. Under the proposed regulations, however, we would evaluate whether an organism would require a permit for movement based on the characteristics of the organism itself rather than on the method by which the organism is genetically engineered. Based on the proposed change in approach, the Agency believes the petition process is no longer necessary and is proposing to remove the petition process from the regulations.

Some commenters advocated that we retain the existing regulatory framework rather than adopting the one we proposed. In the view of one commenter, the proposed rule constituted a shift from a streamlined, performance-based regulatory approach to a more prescriptive one. The commenter saw that shift as a step backwards. Another commenter expressed a preference

for the process-based approach of the existing regulations rather than the product-based one that we proposed. The commenter stated that APHIS should regulate biotechnology products based on the process by which they are created, using genetic engineering as the trigger for regulatory review, to ensure that none evade oversight entirely.

For reasons discussed at length in this document and in the June 2019 proposed rule, we do not agree with these comments.

One commenter viewed our overall regulatory approach as not sufficiently flexible to take into account the relative risk levels associated with different crops. The commenter recommended that we consider such differences when making determinations about the appropriate levels of regulation for different crops.

We do not agree with this comment. Our assessment of the risks associated with specific GE crops will reflected in our RSR determinations and in the permit conditions we assign.

One commenter stated that our policy on low-level prevalence, discussed in the 2008 proposal, is absent from this one.

APHIS intends to continue its support of the trade agencies to address low level presence issues.

One commenter stated that the June 2019 proposed rule lacked the summary of commenters that is common to proposed rules from other agencies. The commenter stated that APHIS should publish such a summary in the final rule and should hold at least one public consultation with stakeholders that do not have a direct or indirect financial interest in the proposed regulations.

We do not agree with this comment. As we noted in the preamble to the June 2019 proposed rule: "Following the withdrawal of the January 2017 proposed rule, APHIS conducted

extensive outreach to Land Grant and public university researchers, as well as small-scale biotechnology developers, agriculture innovators, and other interested stakeholders. In total, APHIS met with more than 80 organizations, including 17 universities, State Departments of Agriculture, and farmer organizations."

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the processes in this final rule, we have prepared a final environmental impact statement (EIS). The final EIS is based on a draft EIS, which we drafted after soliciting public comment through a notice in the Federal Register to help us delineate the scope of the issues and alternatives to be analyzed. The final EIS responds to public comments, analyzes each alternative and its environmental consequences, if any, and provides APHIS' preferred alternative. The EIS was prepared in accordance with: (1) NEPA, as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Copies of the final EIS are available on the Regulations.gov website (see footnote 2 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

Executive Orders 12866, 13563, 13771 and Regulatory Flexibility Act

This final rule is expected to be an Executive Order 13771 deregulatory action. Details on the estimated costs of this final rule can be found in the rule's economic analysis.

This final rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides a final regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available on the Regulations.gov website (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

This final rule codifies the framework for more focused, risk-based regulation of the GE organisms that pose plant pest risk than we had under the previous regulations. Under this rule, certain categories of GE plants are exempted from the regulations in part 340. Developers are able to determine, when appropriate, whether their products fit into one of the exempted categories and are therefore not subject to APHIS' regulations.

The rule also provides for a process to determine the regulatory status of a plant under part 340. GE plants having the same plant-trait-MOA combination as those previously found by APHIS to be not subject to the regulations will not be regulated, nor will they be required to undergo an RSR. GE plants found likely to pose a plant pest risk will only be allowed to move

under permit. For GE plants that do not fall into one of the exempted categories or have not previously been reviewed for plant pest risks by means of an RSR, developers have the option of either requesting an RSR or requesting a permit for the movement, importation, interstate movement, or environmental release of their GE organism. Developers of GE organisms that are plant pests will continue to need permits to import, move interstate, or environmentally release those organisms. Shipping standards under this rule are less prescriptive and more generally applicable, and the rule provides for the issuance of multi-year permits. The provisions for record retention, compliance and enforcement have been strengthened in order to manage compliance with the regulations more efficiently, to augment the approaches that can be used to prevent or remediate risks of plant pests, and to utilize appropriate enforcement strategies. These changes improve the efficiency and clarity of the regulations.

The amendments in this rule will benefit developers, producers, and consumers of certain GE organisms, public and private research entities, and the Agency. There will be no decrease in the level of protection provided against plant pest risks. The regulatory framework, including the RSR process used to determine regulatory status established under this rule, will provide cost savings to GE plant developers and allow for reallocation of APHIS resources to Biotechnology Regulatory Services (BRS) priorities.

Under this rule, APHIS regulatory oversight (through permitting) will not be required for a GE plant that falls into one of the exempted categories or has been assessed through the RSR process and found unlikely to pose an increased plant pest risk relative to its comparator plant. Direct regulatory costs to GE plant developers will be reduced for the development of GE plants for which APHIS permits are no longer necessary. Savings to the regulated community will result from a reduced need to collect field data, fewer reporting requirements, and lower

management costs. Costs now associated with petitions for non-regulated status will be reduced or eliminated where APHIS permits are no longer necessary.

Cost savings for these entities are expected to more than offset the new costs. APHIS estimated the cost savings for two regulatory oversight scenarios, based on a study of the costs encountered by private biotechnology developers as they pursue regulatory authorization of their innovations. When only APHIS has regulatory oversight, compliance cost savings under the rule could range from $1.5 million to $5.6 million ($3.6 million on average) for the development of a given GE plant. If EPA and/or FDA also have an oversight role in the development of a given GE plant, compliance cost savings could range from $538,000 to $924,000 ($730,600 on average). From 1992 through September 2019, an average of just under 5 petitions were processed (granted non-regulated status or the petition withdrawn) in a given year, with a high of 14 in 1995. As the rule is expected to spur innovation, we expect the number of new GE plants developed annually to increase over time. In particular, the rule may provide impetus for the development of new horticultural varieties, where the costs of acquiring non-regulated status in the past may have been prohibitively high relative to the potential market.

In the following estimate of impacts, we use the average cost savings reported above per GE plant developed and assume the annual number of new GE plants developed under the rule without APHIS permits ranges from 5 (the current annual average number of processed petitions) to 10 (twice this average). We further assume that about 20 percent of those new GE plants will require only APHIS oversight, and the remaining will still require FDA and/or EPA oversight. If 5 new GE plants are developed annually without APHIS permits (all with no APHIS permit, but 4 still with EPA and/or FDA evaluation), the annual savings will be $6.5

million.[8] If 10 new GE plants are developed annually without APHIS permits (all with no APHIS permit, but 8 still with EPA and/or FDA evaluation), the annual savings will be $13.0 million.[9]

New costs borne by regulated entities under the rule will include rule familiarization and recordkeeping. Annual recordkeeping costs are based on information collection categories in the paperwork burden section of the rule, and are estimated to total about $714,000. About 1,250 distinct entities have applied for permits or notifications under part 340. APHIS estimates that those entities will spend about 8 hours becoming familiar with the provisions of this rule at a total one-time cost of about $650,000.

In accordance with guidance on complying with EO 13771, the primary estimate of the annual net private sector cost savings for this rule is $9.0 million. This value is the mid-point estimate of the net private cost savings annualized in perpetuity using a 7 percent discount rate.

Current annual APHIS personnel costs for conducting genetic engineering related activities that will be affected by this rule total about $3.4 million. These include compliance activities, inspection activities, 'Am I Regulated' (AIR) process activities, notification activities, permit activities, and petition activities. Under this rule, APHIS' overall annual personnel costs of regulating GE plants are not expected to change. While the volume of specific activities would change, the overall volume of regulatory activities, the general nature of those activities, and the level the skills necessary to perform those activities will not.

Costs to APHIS of implementing this rule include outreach activities, developing guidance documents, training, and adjusting the permit system. APHIS estimates that public outreach, guidance and training will cost about $77,000. Requests for regulatory status and

[8] One x $3,560,245 = $3,560,245. Four x $730,600 = $2,922,400. $3,560,245 + $2,922,400 = $6,482,645.
[9] Two x $3,560,245 = $7,120,490. Eight x $730,600 = $5,844,800. $7,120,490 + $5,844,800 = $12,965,290.

response letters under the rule will be handled in a manner similar to the current AIR process, outside the electronic permitting system and without incurring new costs.

Certain plants are genetically engineered in order to produce pharmaceutical and industrial compounds, also known as plant-made pharmaceuticals and industrials (PMPIs). GE PMPI-producing plants that currently have APHIS permits will not require regulation if an RSR determines they are unlikely to pose a plant pest risk. However, like any other GE plant submitted for an RSR, a PMPI would be subject to the regulations if we find that there is a plausible pathway to increased plant pest risk relative to its comparator and we cannot determine that the GE plant is unlikely to pose an increased risk. This approach reflects our current thinking regarding the implementation of our existing authority under 7 CFR 340 in relation to PMPIs. APHIS will continue to explore additional options for regulatory oversight of PMPIs under the authority provided in the PPA, as appropriate. Federal oversight of outdoor plantings of PMPI-producing plants helps prevent the introduction into the human or animal food supply of PMPI products, even when the principal purpose of the plants is not for human or animal food use. APHIS estimates that current PMPI inspections cost roughly $26,000 in total annually or about $800 each on average. Assuming that oversight continues in the same manner as current APHIS oversight, a similar government expenditure could be expected under any Federal PMPI oversight scenario.

Certain plants are genetically engineered to produce PIPs, meaning that they produce pesticides. APHIS has regulated those PIP-producing plants that are captured by our previous regulations, i.e., when plant pests or plant pest sequences are used. PIPs also fall under the regulatory oversight of EPA. However, only APHIS has exercised regulatory oversight of PIP plantings on 10 acres or less of land. Under this rule, GE PIP-producing plants that are unlikely

to pose an increased plant pest risk relative to their comparators would not be regulated by APHIS following an RSR. This rule will therefore shift Federal oversight of those GE PIPs solely to EPA. EPA may decide to require experimental use permits (EUP) for all, some, or none of such PIPs, and may conduct inspections of all, some, or none of those PIPs under permit. As described above, current inspection costs incurred by APHIS average roughly $800 per inspection.

A quicker APHIS evaluation process will mean a shorter period of regulatory uncertainty that may facilitate developers' ability to raise venture capital. Reduced regulatory requirements may also lead to greater participation by public and private academic institutions in genetic engineering research and product development. These indirect benefits of the rule may spur genetic engineering innovations, particularly in small acreage crops where genetic engineering has not been widely utilized due to the expense of regulation.

GE crop varieties, in general, are not required to be reviewed or approved for safety by the FDA before going to market. However, the developer is responsible for ensuring product safety, and some developers consider voluntary consultations with FDA on food safety to be an absolute necessity for applicable GE products.[10] It will be in a GE plant developer's own best interest to maintain the same level of supervision and control over the development process as at present to prevent undesired cross-pollination or commingling with non-GE crops. Developers also have various legal, quality control and marketing motivations to maintain rigorous voluntary stewardship measures. APHIS therefore believes that developers will continue to utilize such measures for field testing even in cases where APHIS does not require a permit.

[10] *Genetically Engineered Crops: Past Experience and Future Prospects.* Committee on Genetically Engineered Crops: Past Experience and Future Prospects; Board on Agriculture and Natural Resources; Division on Earth and Life Studies; National Academies of Sciences, Engineering, and Medicine.

Farmers who adopt GE crops may benefit from the rule. The adoption of GE crops in the United States has generally reduced costs and improved profitability at the farm level. As mentioned, under this rule, regulatory costs are expected to be lower, thereby potentially spurring developer innovation, especially among small companies and universities. Farmers may benefit by having access to a wider variety of traits as well as a greater number of new GE crop species, affording them a broader selection of crops to suit their particular management objectives. Among the types of innovations expected are crops with greater resistance to disease and insect pests; greater tolerance of stress conditions such as drought, high temperature, low temperature, and salt; and more efficient use of fertilizer. These types of traits can lower farmer input costs (water, fertilizer, pesticide) and increase yields during times of adverse growing conditions.

In addition to the compliance costs associated with regulation, there are opportunity costs of delayed innovation if the approval process for a plant is longer than necessary to ensure safety with reasonable scientific certainty. Regulatory delays mean that the benefits of innovation occur later than they otherwise would have and most likely at lower levels. The forgone benefits due to delayed innovation can be substantial, and developers, producers and consumers all lose from regulatory delays. The foregone benefits stemming from even a relatively brief delay in product release can overshadow both research and regulatory costs.

It should be noted that while the rule will alter APHIS' evaluation process of GE plants, it is not expected to affect the evaluation by FDA or EPA or foreign regulatory agencies, all of whom may affect the opportunity costs of regulatory delay. When FDA and/or EPA also have a regulatory role, time savings will only be realized in those instances in which the APHIS process takes the longest time. When APHIS is the only agency with oversight, such as for new horticultural varieties, there could be significant time savings over the current petition process.

Some farmers (e.g., growers of identity preserved crops, including organic, other non-GE and other agricultural commodities segregated for specific purity and quality tolerances) could be indirectly negatively impacted by these same innovations. Identity preservation (IP) refers to a process or system of maintaining the segregation and documenting the identity of a product. Crops with unique product quality traits, like high oil corn and low linolenic canola require IP to capture the added value. Similarly, organic commodities must be produced according to specific criteria and segregated in the marketplace in order to receive premium prices. Some consumers choose not to purchase products derived from GE crops and instead purchase commodities such as those labeled organic or "non-GMO" (food made without ingredients that were derived from GE organisms). In addition, the organic standard does not allow for the use of GE seeds. When crops intended for the non-GE or other identity-preserved marketplaces contain unintended GE products, their profitability may be diminished.

Effects of this rule on the variety of GE crop species grown in the United States and their wider adoption may increase the possibility of cross-pollination or commingling. As acreage of any given GE crop increases and as a greater variety of crops are modified using genetic engineering, the potential for more instances of unintended presence of a GE organism increases. Unauthorized releases of regulated GE crop plants and the entry of regulated plant material in the commercial food and feed supply can have impacts on domestic or international markets. While such releases have occurred and may occur again, such incidents are expected to be rare.

Entities potentially affected by the rule fall under various categories of the North American Industry Classification System. While economic data are not available on business size for some entities, based on industry data obtained from the Economic Census and the

Census of Agriculture, we can assume that the majority of the businesses affected by the rule will be small.

The following table provides a summary statement of the expected direct costs and cost savings of the rule:

Expected Costs and Costs Savings of the Rule for the Biotechnology Industry and for APHIS, 2016 dollars

Biotechnology Industry		
One-time industry-wide costs of rule familiarization	$650,000	
Annual industry-wide recordkeeping costs	$714,000	
Developer Savings per Trait[1]	Lower Bound Estimate	Upper Bound Estimate
APHIS sole regulatory oversight	$1,546,000	$5,574,000
APHIS oversight together with FDA and/or EPA oversight	$538,000	$924,000
APHIS Biotechnology Regulatory Services		
Annual costs for public outreach, training, and e-permitting[2]	$77,000	

[1] These savings are shown on a per trait basis. On average, if 5 new GE plants are developed annually without APHIS permits (all with no APHIS permit, but 4 still with EPA and/or FDA evaluation), the annual savings will be $6.5 million. If 10 new GE plants are developed annually without APHIS permits (all with no APHIS permit, but 8 still with EPA and/or FDA evaluation), the annual savings will be $13.0 million.

[2] Requests for regulatory status and response letters under the rule will be handled in a manner similar to the current 'Am I Regulated' process, outside the electronic permitting system and without incurring new costs.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 13175

The USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian tribes and determined that this rule has tribal implications; however, OTR has determined that tribal consultation under EO 13175 is not required at this time.

If a tribe requests consultation, APHIS will work with the OTR to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the reporting and recordkeeping requirements included in this final rule have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, we will publish a document in the *Federal Register* providing notice of the assigned OMB control numbers or, if approval is denied, providing notice of what action we plan to take.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this

rule, please contact Mr. Joe Moxey, APHIS' Information Collection Coordinator, at (301) 851-2483.

List of Subjects

7 CFR part 330

Customs duties and inspection, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR part 340

Administrative practice and procedure, Packaging and containers, Plant diseases and pests, Reporting and recordkeeping requirements, Transportation.

7 CFR part 372

Environmental impact statements.

Accordingly, we are amending 7 CFR parts 330, 340 and 372 as follows:

1. The authority citation for part 330 continues to read as follows:

Authority: 7 U.S.C. 1633, 7701-7772, 7781-7786, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

2. In § 330.200, paragraph (b), introductory text, and paragraph (d) are revised to read as set forth below.

§ 330.200 *Scope and general restrictions*.

* * * * *

(b) *Plant pests regulated by this subpart*. For the purposes of this subpart, and except for an organism that has undergone genetic engineering as defined in 7 CFR 340.3, APHIS will consider an organism to be a plant pest if the organism directly or indirectly injures, causes damage to, or causes disease in a plant or plant product, or if the organism is an unknown risk to plants or plant products, but is similar to an organism known to directly or indirectly injure,

cause damage to, or cause disease in a plant or plant product. Plant pests that have undergone genetic engineering, as defined in 7 CFR 340.3, are subject to the regulations of that part.

* * * * *

(d) Paragraph (c) of this section notwithstanding, biological control organisms that have undergone genetic engineering, as defined in 7 CFR 340.3, as well as products that are currently under an EPA experimental use permit, a Federal Insecticide Fungicide and Rodenticide Act (FIFRA) section 18 emergency exemption, or products that are currently registered with EPA as a microbial pesticide product, are not regulated under this subpart. Additionally, biological control organisms that are pesticides that are not registered with EPA, but are being transferred, sold, or distributed in accordance with EPA's regulations in 40 CFR 152.30, are not regulated under this subpart for their interstate movement or importation. However, an importer desiring to import a shipment of biological control organisms subject to FIFRA must submit to the EPA Administrator a Notice of Arrival of Pesticides and Devices as required by CBP regulations at 19 CFR 12.112. The Administrator will provide notification to the importer indicating the disposition to be made of shipment upon its entry into the customs territory of the United States.

3. Part 340 is revised to read as follows:

PART 340—MOVEMENT OF ORGANISMS MODIFIED OR PRODUCED THROUGH GENETIC ENGINEERING

Sec.

340.5 Permits.

340.6 Record retention, compliance, and enforcement.

340.7 Confidential business information.

340.8 Costs and charges.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

§ 340.1 Applicability of this part.

(a) The regulations in this part apply to those genetically engineered (GE) organisms described in § 340.2.

(b) The regulations in this part do not apply to plants that have been modified such that they contain either a single modification of a type listed in paragraphs (b)(1) through (b)(3) of this section, or additional modifications as determined by the Administrator, and described in (b)(4).

(1) The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or

(2) The genetic modification is a targeted single base pair substitution; or

(3) The genetic modification introduces an allele known to occur in the plant's gene pool, or makes changes in a targeted sequence to correspond to such an allele.

(4)(i) The Administrator will determine the additional modifications allowed, based on what could be achieved through traditional plant breeding. The list specifying the additional modifications allowed will be posted on the APHIS website at https://www.aphis.usda.gov/aphis/ourfocus/biotechnology.

(ii) When the Administrator proposes an update to the modifications allowed based on what could be achieved through traditional plant breeding, APHIS will publish, in the notice section of the *Federal Register*, a notice proposing to update the list of modifications. The notice will request public comment.

(iii) After reviewing the comments, APHIS will publish a subsequent notice in the notice section of the *Federal Register* announcing its determination and responding to the comments received.

(c) The regulations in this part do not apply to a GE plant with a plant-trait-mechanism of action combination that has previously undergone an analysis by APHIS in accordance with § 340.4 and is not subject to the regulations.

(d) Developers may request confirmation from APHIS that a plant is not within the scope of this part. APHIS will provide a written response within 120 days of receiving a sufficiently detailed confirmation request, except in circumstances that could not reasonably have been anticipated.

§ 340.2 Scope of this part.

Except under a permit issued by the Administrator in accordance with § 340.5, no person shall move any GE organism that:

(a) Is a plant that has a plant-trait-mechanism of action combination that has not been evaluated by APHIS in accordance with § 340.4 or that, as a result of such evaluation, is subject to the regulations; or

(b) Meets the definition of a *plant pest* in § 340.3; or

(c) Is not a plant but has received deoxyribonucleic acid (DNA) from a plant pest, as defined in § 340.3, and the DNA from the donor organism either is capable of producing an

infectious agent that causes plant disease or encodes a compound that is capable of causing plant disease; or

(d) Is a microorganism used to control plant pests or an invertebrate predator or parasite (parasitoid) used to control invertebrate plant pests and could pose a plant pest risk.

§ 340.3 Definitions.

Terms used in the singular form in this part shall be construed as the plural, and vice versa, as the case may demand. The following terms, when used in this part, shall be construed, respectively, to mean:

Access. The ability during regular business hours to enter, or pass to and from, a location, inspect, and/or obtain or make use or copies of any records, data, or samples necessary to evaluate compliance with this part and all conditions of a permit issued in accordance with § 340.5.

Administrator. The Administrator of the Animal and Plant Health Inspection Service (APHIS) or any other employee of APHIS to whom authority has been or may be delegated to act in the Administrator's stead.

Agent. A person who is designated by the responsible person to act in whole or in part on behalf of the permittee to maintain control over an organism under permit during its movement and ensure compliance with all applicable permit conditions and the requirements in this part. Multiple agents may be associated with a single responsible person or permit. Agents may be, but are not limited to, brokers, farmers, researchers, or site cooperators. An agent must be at least 18 years of age and be a legal resident of the United States.

Animal and Plant Health Inspection Service (APHIS). An agency of the United States Department of Agriculture.

Article. Any material or tangible object that could harbor plant pests.

Contained facility. A structure for the storage and/or propagation of living organisms designed with physical barriers capable of preventing the escape of the organisms. Examples include but are not limited to laboratories, growth chambers, fermenters, and containment greenhouses.

Donor organism. The organism from which genetic material is obtained for transfer to the recipient organism.

Environment. All the land, air, and water; and all living organisms in association with land, air, and water.

Genetic engineering. Techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome.

Import (importation). To move into, or the act of movement into, the territorial limits of the United States.

Inspector. Any individual authorized by the Administrator or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

Interstate. From one State into or through any other State or within the District of Columbia, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Mechanism of action (MOA). The biochemical process(es) through which genetic material determines a trait.

Move (moving, movement). To carry, enter, import, mail, ship, or transport; aid, abet, cause, or induce the carrying, entering, importing, mailing, shipping, or transporting; to offer to carry, enter, import, mail, ship, or transport; to receive to carry, enter, import, mail, ship, or transport; to release into the environment; or to allow any of the above activities to occur.

Organism. Any active, infective, or dormant stage of life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

Permit. A written authorization, including by electronic methods, by the Administrator to move organisms regulated under this part and associated articles under conditions prescribed by the Administrator.

Person. Any individual, partnership, corporation, company, society, association, or other organized group.

Plant. Any plant (including any plant part) for or capable of propagation, including a tree, a tissue culture, a plantlet culture, pollen, a shrub, a vine, a cutting, a graft, a scion, a bud, a bulb, a root, or a seed.

Plant pest. Any living stage of a protozoan, nonhuman animal, parasitic plant, bacterium, fungus, virus or viroid, infectious agent or other pathogen, or any article similar to or allied with any of the foregoing, that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product.

Plant pest risk. The potential for direct or indirect injury to, damage to, or disease in any plant or plant product resulting from introducing or disseminating a plant pest, or the potential for exacerbating the impact of a plant pest.

Plant product. Any flower, fruit, vegetable, root, bulb, seed, or other plant part that is not included in the definition of plant or any manufactured or processed plant or plant part.

Recipient organism. The organism whose nucleic acid sequence will be modified through the use of genetic engineering.

Release into the environment (environmental release). The use of a GE organism outside the physical constraints of a contained facility.

Responsible person. The person responsible for maintaining control over a GE organism under permit during its movement and ensuring compliance with all conditions contained in any applicable permit as well as other requirements in this part. A responsible person may be, but is not limited to, the signatory of a permit, or the institution the signatory represents at the time of application. A signatory must be at least 18 years of age and be a legal resident of the United States.

Secure shipment. Shipment in a container or a means of conveyance of sufficient strength and integrity to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation.

State. Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territories or possession of the United States.

State or Tribal regulatory official. State or Tribal official with responsibilities for plant health, or any other duly designated State or Tribal official, in the State or on the Tribal lands where the movement is to take place.

Trait. An observable (able to be seen or otherwise identified) characteristic of an organism.

Unauthorized release. The intentional or accidental movement of an organism under a permit issued pursuant to this part in a manner not authorized by the permit; or the intentional or accidental movement without a permit of an organism that is subject to the regulations in this part.

§ 340.4 Regulatory status review.

(a)(1) Any person may submit a request to APHIS for a regulatory status review, pursuant to § 340.4(b)(3) of this section.

(2) Any person may request re-review of a GE plant previously found to be subject to this part, provided that the request is supported by new, scientifically valid evidence bearing on the plant pest risk associated with movement of the plant.

(3) APHIS may also initiate a regulatory status review or re-review of a GE plant to identify whether it is subject to regulation under this part.

(4) Information submitted in support of a request for a regulatory status review or re-review must meet the requirements listed in paragraphs (a)(4)(i) through (a)(4)(iii) below.

(i) A description of the comparator plant, to include genus, species, and any relevant subspecies information;

(ii) The genotype of the modified plant, including a detailed description of the differences in genotype between the modified and unmodified plant; and

(iii) A detailed description of the new trait(s) of the modified plant.

(iv) Detailed information on how to meet the above-listed requirements can be found on the APHIS website at https://www.aphis.usda.gov/aphis/ourfocus/biotechnology. Proposed revisions to the detailed information on the APHIS website will be made available for notice and public comment prior to implementation.

(b)(1) When APHIS receives a request for a regulatory status review of a GE plant, the Agency will conduct an initial review to determine whether there is a plausible pathway by which the GE plant, or any sexually compatible relatives that can acquire the engineered trait from the GE plant, could pose an increased plant pest risk relative to the plant pest risk posed by the respective non-GE or other appropriate comparator(s), based on the following factors:

(i) The biology of the comparator plant and its sexually compatible relatives;

(ii) The trait and mechanism-of-action of the modification(s); and

(iii) The effect of the trait and mechanism-of-action on:

(A) The distribution, density, or development of the plant and its sexually compatible relatives;

(B) The production, creation, or enhancement of a plant pest or a reservoir for a plant pest;

(C) Harm to non-target organisms beneficial to agriculture; and

(D) The weedy impacts of the plant and its sexually compatible relatives.

(2) APHIS will complete the initial review within 180 days of receiving a request for a regulatory status review that meets the requirements specified in §340.4(a)(4), except in circumstances that could not reasonably have been anticipated. If the Agency does not identify a plausible pathway by which the GE plant or its sexually compatible relatives could pose an increased plant pest risk relative to the comparator(s) in the initial review, the GE plant is not subject to the regulations in this part. APHIS will post the plant, trait, and general description of the MOA on its website.

(b)(3)(i) If the Agency does identify a plausible pathway by which the GE plant or its sexually compatible relatives could pose an increased plant pest risk relative to the comparator(s)

in the initial review, the requestor may apply for a permit and/or request that APHIS conduct an evaluation of the factor(s) of concern identified in the initial review to determine the likelihood and consequence of the increased plant pest risk.

(ii) For those GE plants for which such an evaluation is conducted, APHIS will publish the results of the evaluation in the *Federal Register* and will solicit and review comments from the public. Except in circumstances that could not reasonably have been anticipated, APHIS will complete these steps within 15 months of receiving a request for a regulatory status review that meets the requirements specified in §340.4(a)(4).

(iii) If APHIS finds that the GE plant and its sexually compatible relatives are unlikely to pose an increased plant pest risk relative to their comparator(s), the GE plant is not subject to this part. APHIS will publish its evaluation of the plant-trait-MOA combination in a subsequent *Federal Register* notice and will also post it on the APHIS website. If APHIS does not make such a finding, the GE plant will remain regulated under this part and its movement will be allowed only under permit in accordance with § 340.5.

§ 340.5 Permits.

(a) *Permit requirement.* A permit from APHIS is required for the movement of all GE organisms subject to the regulations under this part.

(b) *Permit application requirements and permitting exemptions.* All applications for permits must be submitted in accordance with this final rule. The responsible person must apply for and obtain a permit through APHIS' website. The application must also include the following information:

(1) *General information requirements for all permit applications.* All permit applications must include the name, title, and contact information of the responsible person and agent; the

country and locality where the organism was collected, developed, manufactured, reared, cultivated, or cultured; the intended activity (i.e., importation, interstate movement, or release into the environment of the GE organism); and information on the intended trait and the genotype of the intended trait. APHIS may require additional information as necessary to determine whether or not to issue a permit.

(2) *Information requirements for permit applications for interstate movement or importation.* Applications for permits for interstate movement or importation of GE organisms must include the following additional information:

(i) The origin and destination of the GE organism, including information on the addresses and contact details of the sender and recipient, if different from the responsible person;

(ii) The method of shipment, and means of ensuring the security of the shipment against unauthorized release of the organism; and

(iii) The manner in which packaging material, shipping containers, and any other material accompanying the organism will be disposed of to prevent unauthorized release.

(3) *Information requirements for permit applications for release into the environment.* Applications for permits for release of GE organisms into the environment must include information on the size of all proposed environmental release sites, including area, geographic coordinates, addresses, and land use history of the site and adjacent areas; and the name and contact information of a person at each environmental release site, if different from the responsible person. In the event that additional release sites are requested after the issuance of a permit, APHIS will evaluate and amend permits as appropriate, in accordance with paragraph (k) of this section.

(c) *Exemption for GE Arabidopsis thaliana*. A permit for interstate movement is not required for GE *Arabidopsis thaliana*, provided that it is moved as a secure shipment, the modified genetic material is stably integrated into the plant genome, and the modified material does not include the complete infectious genome of a plant pest.

(d) *Exemption for GE disarmed Agrobacterium* species. A permit for interstate movement is not required for any GE disarmed *Agrobacterium* species, provided that it is moved as a secure shipment, the modified genetic material is stably integrated into the genome, and the modified material does not include the complete infectious genome of a plant pest.

(e) *Exemption for Drosophila melanogaster.* A permit for importation or interstate movement is not required for GE *Drosophila melanogaster*, provided that it is moved as a secure shipment and any introduced genetic material is not designed to propagate through a population by biasing the inheritance rate.

(f) *Exemption for certain microbial pesticides.* A permit is not required for any GE microorganism that is currently registered with the Environmental Protection Agency as a microbial pesticide so long as it is not a plant pest as defined in § 340.3.

(g) *Administrative actions*. (1) *Review of permit applications.* APHIS will review the permit application to determine if it is complete. APHIS will notify the applicant orally or in writing if the application is incomplete, and the applicant will be provided the opportunity to revise the application. Once an application is complete, APHIS will review it to determine whether to approve or deny the application.

(2) *APHIS assignment of permit conditions*. If a permit application is approved, the Administrator will issue a permit with conditions as described in paragraph (h) of this section. Prior to issuance of a permit, the responsible person must agree in writing, in a manner

prescribed by the Administrator, that the responsible person and all agents of the responsible person are aware of, understand, and will comply with the permit conditions. Failure to comply with this provision will be grounds for the denial of a permit.

(3) *Inspections*. All premises associated with the permit are subject to inspection before and after permit issuance, and all materials associated with the movement are subject to sampling after permit issuance. The responsible person and agents must provide inspectors access to premises, facilities, release locations, storage areas, waypoints, materials, equipment, means of conveyance, documents, and records related to the movement of organisms permitted under this part. Failure to provide access for inspection prior to the issuance of a permit will be grounds for the denial of a permit. Failure to provide access for inspection following permit issuance will be grounds for withdrawal of the permit.

(4) *State or Tribal review and comment*. The Administrator will submit for notification and review a copy of the permit application, without confidential business information (CBI), and any permit conditions to the appropriate State or Tribal regulatory official. Timely comments received from the State or Tribal regulatory official will be considered by the Administrator prior to permit issuance.

(5) Except in circumstances that could not reasonably have been anticipated, APHIS will approve or deny the permit within:

(i) 45 days of receipt of a complete application for a permit for interstate movement or for importation; or

(ii) 120 days of receipt of a complete application for a permit for release into the environment.

(iii) The 120-day period may also be extended if preparation of an environmental assessment or environmental impact statement is necessary.

(h) *Permit conditions*. The standard conditions listed in this paragraph will be assigned to all permits issued under this section. The Administrator may assign supplemental permit conditions as deemed necessary to ensure confinement of the GE organism. Prior to issuance of an amended permit, the responsible person will be required to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the permit, as described below. If the responsible person does not agree to the conditions, the amendment will be denied.

(1) The organism under permit must be maintained and disposed of in a manner so as to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment.

(2) The organism under permit must be kept separate from other organisms, except as specifically allowed in the permit.

(3) The organism under permit must be maintained only in areas and premises specified in the permit.

(4) The identity of the organism under permit must be maintained and verifiable at all times.

(5) Authorized activities may only be done while the permit is valid; the duration for which the permit is valid will be listed on the permit itself.

(6) Records related to activities carried out under the permit must be maintained by the responsible person and be of sufficient accuracy, quality, and completeness to demonstrate compliance with all permit conditions and requirements under this part. APHIS must be allowed access to all records, to include visual inspection and reproduction (photocopying, digital reproduction, etc.). The responsible person must submit reports and notices to APHIS at the

times specified in the permit and containing the information specified within the permit. At a minimum:

(i) Following an environmental release, environmental release reports must be submitted for all authorized release locations where the release occurred. Environmental release reports must contain details of sufficient accuracy, quality, and completeness to identify the location, shape, and size of the release and the organism(s) released into the environment. In the event no release occurs at an authorized location, an environmental release report of no environmental release must be submitted for all authorized locations where an environmental release did not occur.

(ii) When the environmental release is of a plant, reports of volunteer monitoring activities and findings must be submitted for all authorized release locations where an environmental release occurred. If no monitoring activities are conducted, a volunteer monitoring report of no monitoring must be submitted indicating why no volunteer monitoring was done.

(7) Inspectors must be allowed access, during regular business hours, to all locations related to the permitted activities.

(8) The organism under permit must undergo the application of measures determined by the Administrator to be necessary to prevent its unauthorized release, spread, dispersal, and/or persistence in the environment.

(9) In the event of a possible or actual unauthorized release, the responsible person must contact APHIS as described in the permit within 24 hours of discovery and subsequently supply a statement of facts in writing no later than 5 business days after discovery.

(10) The responsible person for a permit remains the responsible person for the permit unless a transfer of responsibility is approved by APHIS. The responsible person must contact APHIS to initiate any transfer. The new responsible person assumes all responsibilities for ensuring compliance with the existing permit and permit conditions and for meeting the requirements of this part.

(i) *Denial or withdrawal of a permit*. Permit applications may be denied, or permits withdrawn, in accordance with this paragraph.

(1) *Denial of permits*. The Administrator may deny, either orally or in writing, any application for a permit. If the denial is oral, the Administrator will then communicate the denial and the reasons for it in writing as promptly as circumstances allow. The Administrator may deny a permit application if:

(i) The Administrator concludes that the proposed actions, e.g., movements under permit, may not prevent the unauthorized release, spread, dispersal, and/or persistence in the environment of the organism; or

(ii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any provision of this part, any permit that has previously been issued in accordance with this part or any other regulations issued pursuant to the Plant Protection Act, 7 U.S.C. 7701 *et seq*.;

(iii) In addition, no permit will be issued if the responsible person and his or her agents do not agree in writing, in accordance with paragraph (g)(2) of this section, to comply with the permit conditions or, in accordance with paragraph (g)(3) of this section, to allow inspection by APHIS.

(2) *Withdrawal of permits*. The Administrator may withdraw, either orally or in writing, any permit that has been issued. If the withdrawal is oral, the Administrator will communicate the withdrawal and the reasons for it in writing as promptly as circumstances allow. The Administrator may withdraw a permit if:

(i) Following issuance of the permit, the Administrator receives information that would otherwise have provided grounds for APHIS to deny the permit application;

(ii) The Administrator determines that actions taken under the permit have resulted in the unauthorized release, spread, dispersal, and/or persistence in the environment of the organism under permit; or

(iii) The Administrator determines that the responsible person or any agent of the responsible person has failed to comply at any time with any provision of this part or any other regulations issued pursuant to the Plant Protection Act, 7 U.S.C. 7701 *et seq*. This includes failure to comply with the conditions of any permit issued.

(j) *Appeal of denial or withdrawal of permit*. Any person whose permit application has been denied or whose permit has been withdrawn may appeal the decision in writing to the Administrator. The applicant must submit in writing an acknowledgment of the denial or withdrawal and a statement of intent to appeal within 10 days after receiving written notification of the denial or withdrawal. The applicant may request additional time to prepare the appeal. The appeal must state all of the facts and reasons upon which the person relies to assert that the permit was wrongfully denied or withdrawn. The Administrator will grant or deny the appeal in writing, stating the reasons for the decision as promptly as circumstances allow. If there is a conflict as to any material fact, a hearing shall be held to resolve such conflict.

(k) *Amendment of permits*. (1) *Amendment at responsible person's request*. If the responsible person determines that circumstances will change since the permit was initially issued and wishes the permit to be amended accordingly, he or she must request the amendment by contacting APHIS directly. The responsible person will have to provide supporting information justifying the amendment. APHIS will review the amendment request, and may amend the permit if only minor changes are necessary. Requests for more substantive changes may require a new permit application. Prior to issuance of an amended permit, the responsible person will be required to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the amended permit. If the responsible person does not agree to the conditions, the amendment will be denied.

(2) *Amendment initiated by APHIS*. APHIS may amend any permit and its conditions at any time, upon determining that the amendment is needed to address plant pest risks presented by the organism. APHIS will notify the responsible person of the amendment to the permit and, as soon as circumstances allow, the reason(s) for it. The responsible person may have to agree in writing or electronically that he or she and his or her agents will comply with the conditions of the amended permit before APHIS will issue it. If APHIS requests such an agreement, and the responsible person does not accept it, the existing permit will be withdrawn.

(l) *Shipping under a permit*. (1) All shipments of organisms under permit must be secure shipments. Organisms under permit must also be shipped in accordance with the regulations in 49 CFR part 178.

(2) The container must be accompanied by a document that includes the names and contact details for the sender and recipient.

(3) For any organism to be imported into the United States, the outmost container must bear information regarding the nature and quantity of the contents; the country and locality where collected, developed, manufactured, reared, cultivated, or cultured; the name and address of the shipper, owner, or person shipping or forwarding the organism; the name, address, and telephone number of the consignee; the identifying shipper's mark and number; and the permit number authorizing the importation. For organisms imported under permits by mail, the container must also be addressed to a plant inspection station listed in the USDA Plants for Planting Manual, which can be accessed at: https://www.aphis.usda.gov/import_export/plants/manuals/ports/downloads/plants_for_planting.pdf. All imported containers of organisms under permits must be accompanied by an invoice or packing list indicating the contents of the shipment.

(4) Following the completion of the shipment, all packaging material, shipping containers, and any other material accompanying the organism will be devitalized consistent with supplemental permit conditions, or disposed of to prevent unauthorized release.

§ 340.6 Record retention, compliance, and enforcement.

(a) *Recordkeeping*. Responsible persons and their agents are required to establish, keep, and make available to APHIS the following records:

(1) Records and reports required under § 340.5(g);

(2) Addresses and any other information (e.g., GPS coordinates, maps) needed to identify all locations where the organism under permit was stored or used, including all contained facilities and environmental release locations;

(3) A copy of the APHIS permit authorizing the permitted activity; and

(4) Legible copies of contracts between the responsible person and agents that conduct activities subject to this part for the responsible person, and copies of documents relating to agreements made without a written contract.

(b) *Record retention*. Records indicating that an organism under permit that was imported or moved interstate reached its intended destination must be retained for at least 2 years. All other records related to a permit must be retained for 5 years following the expiration of the permit, unless a longer retention period is determined to be needed by the Administrator and documented in the supplemental permit conditions.

(c) *Compliance and enforcement*. (1) Responsible persons and their agents must comply with all of the requirements of this part. Failure to comply with any of the requirements of this part may result in any or all of the following:

(i) Denial of a permit application or withdrawal of a permit in accordance with § 340.5(i);

(ii) Application of remedial measures in accordance with the Plant Protection Act, 7 U.S.C. 7701 *et seq*.; and

(iii) Criminal and/or civil penalties in accordance with the Plant Protection Act, 7 U.S.C. 7701 *et seq*.

(2) Prior to the issuance of a complaint seeking a civil penalty, the Administrator may enter into a stipulation, in accordance with § 380.10 of this chapter.

(d) *Liability for acts of an agent*. For purposes of enforcing this part, the act, omission, or failure of any agent for a responsible person may be deemed also to be the act, omission, or failure of the responsible person.

§ 340.7 Confidential business information.

Persons including confidential business information in any document submitted to APHIS under this part should do so in the following manner. If there are portions of a document deemed to contain confidential business information, those portions must be identified, and each page containing such information must be marked "CBI Copy." A second copy of the document must be submitted with all such CBI deleted, and each page where the CBI was deleted must be marked "CBI Deleted." In addition, any person submitting CBI must justify how each piece of information requested to be treated as CBI is a trade secret or is commercial or financial information and is privileged or confidential.

§ 340.8 Costs and charges.

The services of the inspector related to carrying out this part and provided during regularly assigned hours of duty and at the usual places of duty will be furnished without cost.[1] The U.S. Department of Agriculture will not be responsible for any costs or charges incidental to inspections or compliance with the provisions of this part, other than for the services of the inspector.

PART 372—NATIONAL ENVIRONMENTAL POLICY ACT IMPLEMENTING PROCEDURES

4. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 4321 *et seq.*; 40 CFR parts 1500-1508; 7 CFR parts 1b, 2.22, 2.80, and 371.9.

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[1] The Department's provisions relating to overtime charges for an inspector's services are set forth in part 354 of this chapter.

Done in Washington, DC, this _____ day of _____.

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